

PACKAGE LEAFLET: INFORMATION FOR THE USER
Extra Power Pain Control Caplets
Aspirin, Paracetamol and Caffeine

Read all of this leaflet carefully because it contains important information for you. This medicine is available without prescription. However, you still need to take Extra Power Pain Control Caplets carefully to get the best results from them.

- Keep this leaflet. You may need to read it again while you are receiving your treatment.
- If you have any further questions, please ask your pharmacist.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Extra Power Pain Control Caplets are and what they are used for
2. Before you take Extra Power Pain Control Caplets
3. How to take Extra Power Pain Control Caplets
4. Possible side effects
5. How to store Extra Power Pain Control Caplets
6. Further information

1. What Extra Power Pain Control Caplets are and what they are used for

These caplets contain a combination of aspirin (pain relief and anti-inflammatory), paracetamol (a painkiller) and caffeine (a mild stimulant).

Extra Power Pain Control Caplets are used for relief from mild to moderate pain including headache, migraine, neuralgia, toothache, sore throat, period pains; and symptomatic relief of sprains, strains, rheumatic pain, sciatica, lumbago, fibrositis, muscular aches and pains, joint swelling and stiffness, influenza, feverishness and feverish colds.

2. Before you take Extra Power Pain Control Caplets

You should not take Extra Power Pain Control Caplets if you:

- are allergic (hypersensitive) to aspirin or any other non-steroidal anti-inflammatory drugs (NSAIDs), paracetamol, caffeine or any of the other ingredients in Extra Power Pain Control Caplets (see section 6, Further information). Symptoms may include rhinitis (runny nose, itchy rash, swollen face, mouth or tongue or asthma attack).
- have had ulcers of the stomach or small intestine (peptic ulcer disease)
- suffer from haemophilia, any other blood clotting disorders or are taking any medicines to prevent blood clotting
- suffer from gout.



Talk to your doctor or pharmacist before taking Extra Power Pain Control Caplets if you:

- suffer from kidney disease or liver disease, particularly if caused by alcohol
- suffer from alcoholism
- suffer from asthma, particularly if your asthma is worsened by aspirin
- if you have nasal polyps (inflamed swellings inside the nose)
- if you suffer from indigestion (dyspepsia)
- if you have an infection
- if you are a woman trying to conceive
- suffer from heart disease and/or high blood pressure
- suffer from diabetes
- suffer from glucose-6-phosphate dehydrogenase (G6PD) deficiency (an enzyme deficiency that can cause anaemia)
- are dehydrated.

Caution should be exercised when taking paracetamol products prior to (less than 72 hours before) or at the same time as intravenous busulfan.

Your blood, kidney and liver should be monitored during prolonged use as blood, kidney and liver disorders may develop.

This medicine contains paracetamol; do not take with any other paracetamol-containing products at the same time. Aspirin can increase the time it takes your blood to clot; you should not take this medicine several days before any scheduled surgery appointments.

This medicine should not be given to children under 16 years unless specifically advised by your doctor (e.g. to treat Kawasaki's disease), due to the association between aspirin and Reye's syndrome, a very rare disease that can cause damage to the brain, liver and could be fatal.

This product belongs to a group of medicines which may impair the fertility in women. This effect is reversible on stopping the medicine.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. The following medicines can affect or be affected by Extra Power Pain Control Caplets:

- medicines used to treat bacterial infections (e.g. quinolones such as enoxacin, piperidic acid and ciprofloxacin, sulphonamide antibiotics and isoniazid used to treat tuberculosis)
- medicines used to treat epilepsy (fits) (e.g. carbamazepine, phenobarbital, primidone, sodium valproate). If you take sodium valproate with this medicine you may increase the likelihood of bleeding
- medicines used to treat depression (e.g. fluvoxamine), Selective Serotonin Re-uptake Inhibitors (SSRIs) such as venlafaxine): if taken with aspirin products you may increase the likelihood of bleeding
- medicines used to treat asthma (e.g. theophylline or zafirlukast)
- medicine used to thin the blood and stop the blood clotting (anticoagulants- e.g. warfarin, heparin, streptokinase, clopidogrel and ticlopidine): if you take one of these medicines with aspirin products you may increase the likelihood of bleeding
- medicines used to treat water retention (diuretics - e.g. spironolactone and acetazolamide)
- medicines used to treat high blood pressure (ACE Inhibitors, Angiotensin-II Receptor Antagonists and calcium channel blockers e.g. verapamil): taken with aspirin products these medicines may not be as effective and you may suffer from kidney problems
- medicines used to treat gout (e.g. probenecid or sulfapyrazone). Phenylbutazone may reduce the effect of aspirin products.
- metoclopramide and domperidone (used to treat sickness and nausea)
- oral contraceptives ("The Pill", mini-pill), hormonal implants and HRT
- diflunisal (an anti-inflammatory painkiller)
- colestyramine (used to treat high cholesterol and in diseases of the intestine and liver)
- disulfiram (used to treat alcoholism)
- lithium (used to treat manic depression/bipolar disorder)
- mexilitine (used to treat abnormal heart rhythms)
- fluconazole or terbinafine (used to treat fungal infections)
- clozapine (an antipsychotic used to treat schizophrenia)
- diuretics such as hydrochlorothiazide
- ephedrine, a stimulant used in dietary supplements such as Ma Huang
- thiopental (used as an anaesthetic)
- kaolin (used to treat Diarrhoea)
- methotrexate (used to treat arthritis and cancers)
- benzodiazepine medicines (sedatives e.g. diazepam)
- phenylpropranolamine (a decongestant)
- non-steroidal anti-inflammatory drugs (NSAIDs) (e.g. indometacin or fenoprofen)
- insulin and oral anti-diabetic medicines
- corticosteroids. If you suddenly stop taking corticosteroids you may develop aspirin poisoning
- vitamin C
- gold compounds
- mifepristone used as an emergency contraceptive. Wait 8-12 days after taking mifepristone before taking any aspirin products

- Cilostazol (for leg pain that occurs when walking due to poor circulation): the dose of aspirin should not be greater than 80mg a day
- intravenous busulfan (used in chemotherapy to treat cancer).

Pregnancy and breast-feeding

This medicine should not be taken during pregnancy or whilst breast-feeding. Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machinery

Extra Power Pain Control Caplets do not affect your ability to drive or use machinery.

3. How to take Extra Power Pain Control Caplets

Always follow the instructions on the carton. If you are not sure then ask your doctor or pharmacist for advice. Swallow caplets whole with a glass of water.

Adults, elderly and children over 16 years

- 1 to 2 caplets every 4-6 hours as required
- The dose should not be taken more frequently than every four hours
- do not take more than 8 caplets in 24 hours
- do not exceed the recommended dose
- if symptoms persist see your doctor
- do not take for more than 3 days unless you have been told to do so by your doctor.

Take the caplets with or immediately after food to reduce the risk of getting stomach and bowel irritation.

Do not give to children aged under 16 years, unless specifically advised by your doctor.

If you take more Extra Power Pain Control Caplets than you should

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage. Symptoms of an overdose include vomiting, dehydration, tinnitus, vertigo, headache, nausea, dizziness, restlessness, heart failure, breathing failure, deafness, sweating, warm extremities with racing pulse, increased breathing rate and hyperventilation.

If you forget to take Extra Power Pain Control Caplets

If you forget a dose, take another as soon as you remember. If it is almost time for your next dose, then do not take the missed dose at all. NEVER take a double dose to make up for the one missed.

4. Possible side effects

Like all medicines, Extra Power Pain Control Caplets can cause side effects, although not everybody gets them.

As can happen with any medicine, a few people may develop a serious side effect. If you experience any of the following, stop taking the medicine immediately, and see your doctor or pharmacist:

- allergic reactions which may be severe such as skin rash, peeling of the skin, itching, swollen red areas of the skin, sometimes with shortness of breath or swelling of the mouth, lips, tongue, throat or face.
- Vomiting of blood and/or blood in the faeces, which may result in stomach and gut ulcers or haemorrhage.
- Stevens-Johnson syndrome (symptoms include fever, rash, sore mouth and eyes, joint and muscle aches).
- Toxic epidermal necrolysis (a severe skin problem with shedding of the upper layer).

Side effects that have been reported with Extra Power Pain Control Caplets are:

- rash
- anxiety
- slight blood loss which may result in iron-deficiency anaemia during long term use
- changes in blood cells
- irritability
- increased frequency to urinate
- tinnitus
- indigestion
- asthma attacks
- worsening of asthma
- sleep disturbance
- blood in the urine
- diarrhoea
- irregular heart beat
- insomnia
- lumps (cysts) in the breasts
- deafness
- feeling or being sick
- liver problems
- tremor
- restlessness
- excitement
- palpitations
- acid reflux
- stomach irritation
- very rare cases of serious skin reactions have been reported
- anaemia
- irritation in the nose
- swelling of tissues

Stomach and bowel irritation may be reduced by taking the tablets with or immediately after food.

The use of this medicine over a long time can cause kidney problems. If you experience any side effects or feel that the medicine is affecting you badly tell your doctor or pharmacist immediately.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Extra Power Pain Control Caplets

Keep out of the reach and sight of children.

- Extra Power Pain Control Caplets should be stored in a dry place below 25°C
- Store in the original container to protect from light; do not transfer to another container
- Extra Power Pain Control Caplets should not be taken after the expiry date on the carton; the expiry date refers to the last day of the month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Further information

What Extra Power Pain Control Caplets contain

The active ingredients are: aspirin 300mg, paracetamol 200mg and caffeine 45mg.

The other ingredients are: povidone, hydroxypropylcellulose, stearic acid, microcrystalline cellulose, maize starch, pregelatinised starch, hydroxypropyl methylcellulose 5cPs, hydroxypropyl methylcellulose 15cPs, macrogol 4000.

What Extra Power Pain Control Caplets look like and the contents of the pack

Extra Power Pain Control Caplets are white, coated, capsule shaped tablets.

Extra Power Pain Control Caplets are available from on general sale in blister pack sizes of 12 and 16 caplets.

Marketing Authorisation Holder: Wockhardt UK Limited, Ash Road North, Wrexham LL13 9UF, UK.

Manufacturer: CP Pharmaceuticals Limited, Ash Road North, Wrexham LL13 9UF, UK.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only).

Please be ready to give the following information:

| Product name | Reference number |
|----------------------------------|------------------|
| Extra Power Pain Control Caplets | 29831/0164 |

This is a service provided by the Royal National Institute of Blind People.

Leaflet Prepared: January 2015

GSL

PACKAGE LEAFLET: INFORMATION FOR THE USER

Tesco Extra Power Pain Control Tablets

Aspirin, Paracetamol and Caffeine

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Extra Power Pain Control Tablets carefully to get the best results from them.

- Keep this leaflet. You may need to read it again while you are receiving your treatment.
- If you have any further questions, please ask your pharmacist.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

The name of your medicine is Tesco Extra Power Pain Control Tablets. In the rest of this leaflet it is called Extra Power Pain Control Tablets.

In this leaflet:

1. What Extra Power Pain Control Tablets are and what they are used for
2. Before you take Extra Power Pain Control Tablets
3. How to take Extra Power Pain Control Tablets
4. Possible side effects
5. How to store Extra Power Pain Control Tablets
6. Further information

1. What Extra Power Pain Control Tablets are and what they are used for

The name of your medicine is Extra Power Pain Control Tablets. These tablets contain a combination of aspirin (pain relief and anti-inflammatory), paracetamol (a painkiller) and caffeine (a mild stimulant).

Extra Power Pain Control Tablets are used to relieve the symptoms of the common cold and flu; including fever, and sore throats and are also used to relieve mild to moderate pain including, headache, period pains, and pains associated with the joints and muscles.

2. Before you take Extra Power Pain Control Tablets

You should not take Extra Power Pain Control Tablets if you:

- are allergic (hypersensitive) to aspirin or any other non-steroidal anti-inflammatory drugs (NSAIDs), paracetamol, caffeine or any of the other ingredients in Extra Power Pain Control Tablets (see section 6, Further information). Symptoms may include rhinitis (runny nose, itchy rash, swollen face, mouth or tongue) or asthma attack
- have had ulcers of the stomach or small intestine (peptic ulcer disease)
- suffer from haemophilia, any other blood clotting disorders or are taking any medicines to prevent blood clotting
- suffer from gout.



Talk to your doctor or pharmacist before taking Extra Power Pain Control Tablets if you:

- suffer from kidney disease or liver disease, particularly if caused by alcohol
- suffer from alcoholism
- suffer from asthma, particularly if your asthma is worsened by aspirin
- suffer from heart disease and/or high blood pressure
- if you have nasal polyps (inflamed swellings inside the nose)
- if you suffer from indigestion
- if you have an infection
- if you are a woman trying to conceive
- suffer from diabetes
- suffer from glucose-6-phosphate dehydrogenase (G6PD) deficiency (an enzyme deficiency that can cause anaemia)
- are dehydrated.

Caution should be exercised when taking paracetamol products prior to (less than 72 hours before) or at the same time as intravenous busulfan.

Your blood, kidney and liver should be monitored during prolonged use as blood, kidney and liver disorders may develop.

This medicine contains paracetamol; do not take with any other paracetamol-containing products at the same time. Aspirin can increase the time it takes your blood to clot; you should not take this medicine several days before any scheduled surgery appointments.

This medicine should not be given to children under 16 years unless specifically advised by your doctor (e.g. to treat Kawasaki's disease), due to the association between aspirin and Reye's syndrome, a very rare disease that can cause damage to the brain, liver and could be fatal.

The product belongs to a group of medicines which may impair the fertility in women. This effect is reversible on stopping the medicine.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription. The following medicines can affect or be affected by Extra Power Pain Control Tablets:

- medicines used to treat bacterial infections (e.g. quinolone, such as enoxacin, piperidic acid and ciprofloxacin, sulphonamide antibiotics and isoniazid used to treat tuberculosis)
- medicines used to treat epilepsy (fits) (e.g. carbamazepine, phenobarbital, primidone, sodium valproate)
- medicines used to treat depression (e.g. fluvoxamine), Selective Serotonin Re-uptake Inhibitors (SSRIs) such as venlafaxine: if taken with aspirin products you may increase the likelihood of bleeding.
- medicines used to treat asthma (e.g. theophylline or zafirlukast)
- medicine used to thin the blood and stop the blood clotting (anticoagulants- e.g. warfarin, heparin, streptokinase, clopidogrel and ticlopidine): if you take one of these medicines with aspirin products you may increase the likelihood of bleeding
- medicines used to treat water retention (diuretics - e.g. spironolactone and acetazolamide)
- medicines used to treat high blood pressure (ACE Inhibitors, Angiotensin-II Receptor Antagonists and calcium channel blockers e.g. verapamil): taken with aspirin products these medicines may not be as effective and you may suffer from kidney problems
- medicines used to treat gout (e.g. probenecid or sulfinpyrazone). Phenylbutazone may reduce the effect of aspirin products.
- metoclopramide and domperidone (used to treat sickness and nausea)
- oral contraceptives ("The Pill", mini-pill), hormonal implants and HRT
- diflunisal (an anti-inflammatory painkiller)
- colestyramine (used to treat high cholesterol and in diseases of the intestine and liver)
- disulfaram (used to treat alcoholism)
- lithium (used to treat manic depression/bipolar disorder)
- mexilitine (used to treat abnormal heart rhythms)
- thiopental (used as an anaesthetic)
- kaolin (used to treat Diarrhoea)
- methotrexate (used to treat arthritis and cancers)
- benzodiazepine medicines (sedatives e.g. diazepam)
- phenylpropranolamine (a decongestant)
- non-steroidal anti-inflammatory drugs (NSAIDs) (e.g. indometacin or fenoprofen)
- insulin and oral anti-diabetic medicines
- corticosteroids. If you suddenly stop taking corticosteroids you may develop aspirin poisoning
- vitamin C
- gold compounds
- mifepristone used as an emergency contraceptive. Wait 8-12 days after taking mifepristone before taking any aspirin products.

- Cilostazol (for leg pain that occurs when walking due to poor circulation): the dose of aspirin should not be greater than 80mg a day
- intravenous busulfan (used in chemotherapy to treat cancer).

Pregnancy and breast-feeding

This medicine should not be taken during pregnancy or whilst breast-feeding. Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machinery

Extra Power Pain Control Tablets do not affect your ability to drive and use machinery.

3. How to take Extra Power Pain Control Tablets

Always follow the instructions on the label. If you are not sure then ask your doctor or pharmacist for advice. Swallow tablets whole with a glass of water.

Adults, elderly and children over 16 years

- 1 to 2 tablets every 4-6 hours as required
- do not take more than 8 tablets in 24 hours
- do not exceed the recommended dose
- if symptoms persist see your doctor
- do not take for more than 3 days unless you have been told to do so by your doctor.

Take the tablets with or immediately after food to reduce the risk of getting stomach and bowel irritation.

Do not give to children aged under 16 years, unless specifically advised by your doctor.

If you take more Extra Power Pain Control Tablets than you should

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

Symptoms of an overdose include vomiting, dehydration, tinnitus, vertigo, headache, nausea, dizziness, restlessness, heart failure, breathing failure, deafness, sweating, warm extremities with racing pulse, increased breathing rate and hyperventilation.

If you forget to take Extra Power Pain Control Tablets

If you forget a dose, take another as soon as you remember. If it is almost time for your next dose, then do not take the missed dose at all. NEVER take a double dose to make up for the one missed.

4. Possible side effects

Like all medicines, Extra Power Pain Control Tablets can cause side effects, although not everybody gets them.

As can happen with any medicine, a few people may develop an allergic reaction. If you experience any of the following, stop taking the medicine immediately, and see your doctor or pharmacist:

- allergic reactions which may be severe such as skin rash, peeling of the skin, itching, swollen red areas of the skin, sometimes with shortness of breath or swelling of the mouth, lips, tongue, throat or face.
- Stevens-Johnson syndrome (symptoms include fever, rash, sore mouth and eyes, joint and muscle aches).
- Toxic epidermal necrolysis (a severe skin problem with shredding of the upper layer).
- Vomiting blood and/or blood in the faeces, which may result in stomach and gut ulcers or haemorrhage.

Side effects that have been reported with Extra Power Pain Control Tablets are:

- rash
- anxiety
- excitement
- irregular heart beat
- indigestion
- irritation in the nose
- liver problems
- slight blood loss which
- insomnia
- deafness
- worsening of asthma
- sleep disturbance
- palpitations
- stomach irritation
- diarrhoea
- feeling or being sick
- swelling of tissues
- acid reflux may result in iron-deficiency anaemia during long term use
- lumps (cysts) in the breasts
- irritability
- tremor
- restlessness
- changes in blood cells
- anaemia
- blood in the urine
- asthma attacks
- tinnutus
- increased frequency to urinate
- very rare cases of serious skin reactions have been reported.

Stomach and bowel irritation may be reduced by taking the tablets with or immediately after food.

The use of this medicine over a long time can cause kidney problems. If you experience any side effects or feel that the medicine is affecting you badly tell your doctor or pharmacist immediately.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Extra Power Pain Control Tablets

Keep out of reach and sight of children.

- Extra Power Pain Control Tablets should be stored in a dry place below 25°C
- Store in the original container to protect from light; do not transfer to another container
- Extra Power Pain Control Tablets should not be taken after the expiry date on the label; the expiry date refers to the last day of the month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Further information

What Extra Power Pain Control Tablets contain

The active ingredients are: aspirin 300mg, paracetamol 200mg and caffeine 45mg.

The other ingredients are: povidone, hydroxypropylcellulose, stearic acid, microcrystalline cellulose, maize starch, pregelatinised starch, hydroxypropyl methylcellulose 5cPs, hydroxypropyl methylcellulose 15cPs, macrogol 4000.

What Extra Power Pain Control Tablets look like and the contents of the pack

Extra Power Pain Control Tablets are white, coated, capsule shaped tablets.

Extra Power Pain Control Tablets are available from on general sale in blister pack sizes of 12 and 16 tablets.

Marketing Authorisation Holder: Wockhardt UK Limited, Ash Road North, Wrexham LL13 9UF, UK.

Manufacturer: CP Pharmaceuticals Limited, Ash Road North, Wrexham LL13 9UF, UK.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only).

Please be ready to give the following information:

| Product name | Reference number |
|----------------------------------|------------------|
| Extra Power Pain Control Tablets | 29831/0164 |

This is a service provided by the Royal National Institute of Blind People.

Leaflet Prepared: January 2015

GSL

PACKAGE LEAFLET: INFORMATION FOR THE USER
Wockhardt Dual Action Pain Control Tablets
Aspirin, Paracetamol and Caffeine

Read all of this leaflet carefully because it contains important information for you. This medicine is available without prescription. However, you still need to take Wockhardt Dual Action Pain Control Tablets carefully to get the best results from them.

- Keep this leaflet. You may need to read it again while you are receiving your treatment.
- If you have any further questions, please ask your pharmacist.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

The name of your medicine is Wockhardt Dual Action Pain Control Tablets. In the rest of the leaflet it is called Dual Action Pain Control Tablets.

In this leaflet:

1. What Dual Action Pain Control Tablets are and what they are used for
2. Before you take Dual Action Pain Control Tablets
3. How to take Dual Action Pain Control Tablets
4. Possible side effects
5. How to store Dual Action Pain Control Tablets
6. Further information

1. What Dual Action Pain Control Tablets are and what they are used for

These tablets contain a combination of aspirin (pain relief and anti-inflammatory), paracetamol (a painkiller) and caffeine (a mild stimulant).

Dual Action Pain Control Tablets are used for relief from mild to moderate pain including headache, migraine, neuralgia, toothache, sore throat, period pains; and symptomatic relief of sprains, strains, rheumatic pain, sciatica, lumbago, fibrositis, muscular aches and pains, joint swelling and stiffness, influenza, feverishness and feverish colds.

2. Before you take Dual Action Pain Control Tablets

You should not take Dual Action Pain Control Tablets if you:

- are allergic (hypersensitive) to aspirin or any other non-steroidal anti-inflammatory drugs (NSAIDs), paracetamol, caffeine or any of the other ingredients in Dual Action Pain Control Tablets (see section 6, Further information). Symptoms may include rhinitis (runny nose, itchy rash, swollen face, mouth or tongue or asthma attack).
- have had ulcers of the stomach or small intestine (peptic ulcer disease)
- suffer from haemophilia, any other blood clotting disorders or are taking any medicines to prevent blood clotting
- suffer from gout.



Talk to your doctor or pharmacist before taking Dual Action Pain Control Tablets if you:

- suffer from kidney disease or liver disease, particularly if caused by alcohol
- suffer from alcoholism
- suffer from asthma, particularly if your asthma is worsened by aspirin
- if you have nasal polyps (inflamed swellings inside the nose)
- if you suffer from indigestion (dyspepsia)
- if you have an infection
- if you are a woman trying to conceive
- suffer from heart disease and/or high blood pressure
- suffer from diabetes
- suffer from glucose-6-phosphate dehydrogenase (G6PD) deficiency (an enzyme deficiency that can cause anaemia)
- are dehydrated.

Caution should be exercised when taking paracetamol products prior to (less than 72 hours before) or at the same time as intravenous busulfan.

Your blood, kidney and liver should be monitored during prolonged use as blood, kidney and liver disorders may develop.

This medicine contains paracetamol; do not take with any other paracetamol-containing products at the same time. Aspirin can increase the time it takes your blood to clot; you should not take this medicine several days before any scheduled surgery appointments.

This medicine should not be given to children under 16 years unless specifically advised by your doctor (e.g. to treat Kawasaki's disease), due to the association between aspirin and Reye's syndrome, a very rare disease that can cause damage to the brain, liver and could be fatal.

This product belongs to a group of medicines which may impair the fertility in women. This effect is reversible on stopping the medicine.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. The following medicines can affect or be affected by Dual Action Pain Control Tablets:

- medicines used to treat bacterial infections (e.g. quinolones such as enoxacin, piperimidic acid and ciprofloxacin, sulphonamide antibiotics and isoniazid used to treat tuberculosis)
- medicines used to treat epilepsy (fits) (e.g. carbamazepine, phenobarbital, primidone, sodium valproate). If you take sodium valproate with this medicine you may increase the likelihood of bleeding
- medicines used to treat depression (e.g. fluvoxamine), Selective Serotonin Re-uptake Inhibitors (SSRIs) such as venlafaxine: if taken with aspirin products you may increase the likelihood of bleeding
- medicines used to treat asthma (e.g. theophylline or zafirlukast)
- medicine used to thin the blood and stop the blood clotting (anticoagulants- e.g. warfarin, heparin, streptokinase, clopidogrel and ticlopidine): if you take one of these medicines with aspirin products you may increase the likelihood of bleeding
- medicines used to treat water retention (diuretics - e.g. spironolactone and acetazolamide)
- medicines used to treat high blood pressure (ACE Inhibitors, Angiotensin-II Receptor Antagonists and calcium channel blockers e.g. verapamil): taken with aspirin products these medicines may not be as effective and you may suffer from kidney problems
- medicines used to treat gout (e.g. probenecid or sulfinpyrazone). Phenylbutazone may reduce the effect of aspirin products.
- metoclopramide and domperidone (used to treat sickness and nausea)
- oral contraceptives ("The Pill", mini-pill), hormonal implants and HRT
- diflunisal (an anti-inflammatory painkiller)
- colestyramine (used to treat high cholesterol and in diseases of the intestine and liver)
- disulfiram (used to treat alcoholism)
- lithium (used to treat manic depression/bipolar disorder)
- mexilitine (used to treat abnormal heart rhythms)
- thiopental (used as an anaesthetic)
- kaolin (used to treat Diarrhoea)
- fluconazole or terbinafine (used to treat fungal infections)
- clozapine (an antipsychotic used to treat schizophrenia)
- diuretics such as hydrochlorothiazide
- ephedrine, a stimulant used in dietary supplements such as Ma Huang
- methotrexate (used to treat arthritis and cancers)
- benzodiazepine medicines (sedatives e.g. diazepam)
- phenylpropanolamine (a decongestant)
- non-steroidal anti-inflammatory drugs (NSAIDs) (e.g. indometacin or fenoprofen)
- insulin and oral anti-diabetic medicines
- corticosteroids. If you suddenly stop taking corticosteroids you may develop aspirin poisoning
- vitamin C
- gold compounds

- mifepristone used as an emergency contraceptive. Wait 8-12 days after taking mifepristone before taking any aspirin products
- Cilostazol (for leg pain that occurs when walking due to poor circulation): the dose of aspirin should not be greater than 80mg a day
- intravenous busulfan (used in chemotherapy to treat cancer).

Pregnancy and breast-feeding

This medicine should not be taken during pregnancy or whilst breast-feeding. Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machinery

Dual Action Pain Control Tablets do not affect your ability to drive or use machinery.

3. How to take Dual Action Pain Control Tablets

Always follow the instructions on the carton. If you are not sure then ask your doctor or pharmacist for advice. Swallow tablets whole with a glass of water.

Adults, elderly and children over 16 years

- 1 to 2 tablets every 4-6 hours as required
- The dose should not be taken more frequently than every four hours
- do not take more than 8 tablets in 24 hours
- do not exceed the recommended dose
- if symptoms persist see your doctor
- do not take for more than 3 days unless you have been told to do so by your doctor.

Take the tablets with or immediately after food to reduce the risk of getting stomach and bowel irritation.

Do not give to children aged under 16 years, unless specifically advised by your doctor.

If you take more Dual Action Pain Control Tablets than you should

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

Symptoms of an overdose include vomiting, dehydration, tinnitus, vertigo, headache, nausea, dizziness, restlessness, heart failure, breathing failure, deafness, sweating, warm extremities with racing pulse, increased breathing rate and hyperventilation.

If you forget to take Dual Action Pain Control Tablets

If you forget a dose, take another as soon as you remember. If it is almost time for your next dose, then do not take the missed dose at all. NEVER take a double dose to make up for the one missed.

4. Possible side effects

Like all medicines, Dual Action Pain Control Tablets can cause side effects, although not everybody gets them.

As can happen with any medicine, a few people may develop a serious side effect. If you experience any of the following, stop taking the medicine immediately, and see your doctor or pharmacist:

- Allergic reactions which may be severe such as skin rash, peeling of the skin, itching, swollen red areas of the skin, sometimes with shortness of breath or swelling of the mouth, lips, tongue, throat or face.
- Stevens-Johnson syndrome (symptoms include fever, rash, sore mouth and eyes, joint and muscle aches).
- Toxic epidermal necrolysis (a severe skin problem with shedding of the upper layer).
- Vomiting of blood and/or blood in the faeces, which may result in stomach and gut ulcers or haemorrhage.

Side effects that have been reported with Dual Action Pain Control Tablets are:

- rash
- anxiety
- slight blood loss which may result in iron-deficiency anaemia during long term use
- changes in blood cells
- irritability
- deafness
- lumps (cysts) in the breasts
- indigestion
- asthma attacks
- worsening of asthma
- sleep disturbance
- blood in the urine
- diarrhoea
- irregular heart beat
- insomnia
- very rare cases of serious skin reactions have been reported
- stomach irritation
- feeling or being sick
- liver problems
- tremor
- restlessness
- excitement
- palpitations
- acid reflux
- tinnitus
- increased frequency to urinate
- anaemia
- irritation in the nose
- swelling of tissues

Stomach and bowel irritation may be reduced by taking the tablets with or immediately after food.

The use of this medicine over a long time can cause kidney problems. If you experience any side effects or feel that the medicine is affecting you badly tell your doctor or pharmacist immediately.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dual Action Pain Control Tablets

Keep out of the reach and sight of children.

- Dual Action Pain Control Tablets should be stored in a dry place below 25°C
- Store in the original container to protect from light; do not transfer to another container
- Dual Action Pain Control Tablets should not be taken after the expiry date on the carton; the expiry date refers to the last day of the month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Further information

What Dual Action Pain Control Tablets contain

The active ingredients are: aspirin 300mg, paracetamol 200mg and caffeine 45mg.

The other ingredients are: povidone, hydroxypropylcellulose, stearic acid, microcrystalline cellulose, maize starch, pregelatinised starch, hydroxypropyl methylcellulose 5cPs, hydroxypropyl methylcellulose 15cPs, macrogol 4000.

What Dual Action Pain Control Tablets look like and the contents of the pack

Dual Action Pain Control Tablets are white, coated, capsule shaped tablets.

Dual Action Pain Control Tablets are available from on general sale in blister pack sizes of 12 and 16 caplets.

Marketing Authorisation Holder: Wockhardt UK Limited, Ash Road North, Wrexham LL13 9UF, UK.

Manufacturer: CP Pharmaceuticals Limited, Ash Road North, Wrexham LL13 9UF, UK.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only).

Please be ready to give the following information:

| Product name | Reference number |
|--|------------------|
| Wockhardt Dual Action Pain Control Caplets | 29831/0164 |

This is a service provided by the Royal National Institute of Blind People.

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