

PACKAGE LEAFLET: INFORMATION FOR THE USER

Seractil® 400mg film-coated Tablets (dexibuprofen)

Your medicine is available using the name Seractil 400mg film-coated Tablets but will be referred to as Seractil throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any more questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.*
- *If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.*

What is in this leaflet

1. What Seractil is and what it is used for
2. What you need to know before you take Seractil
3. How to take Seractil
4. Possible side effects
5. How to store Seractil
6. Contents of the pack and other information

1. What Seractil is and what it is used for

Dexibuprofen, the active ingredient in Seractil, belongs to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs such as dexibuprofen are used as a painkiller and to control inflammation. They work by reducing the amount of prostaglandins (substances that control inflammation and pain) your body produces.

What is Seractil used for?

Seractil is used to relieve:

- pain and inflammation caused by osteoarthritis (when your joints become worn);
- period (menstrual) pain;
- mild to moderate pain, such as pains in the muscles and joints and toothaches.

2. What you need to know before you take Seractil

Do not take Seractil if:

- you are allergic to dexibuprofen or any of the other ingredients of this medicine (listed in section 6);
- you are allergic to acetylsalicylic acid or other pain-killers (your allergy may cause you to have difficulty breathing, asthma, a runny nose, a skin rash or swelling to your face);
- you previously had bleedings or perforations in your gastrointestinal system caused by NSAIDs;
- you have, or have ever had, peptic ulceration (ulcer in your stomach or duodenum) or bleeding in your digestive tract;
- you have bleedings in the brain (cerebrovascular bleedings) or other active bleedings;
- you currently have a flare up of an inflammatory disease of the intestines (ulcerative colitis, Crohn's disease);
- you have serious heart failure or serious liver or kidney disease;
- from the beginning of the 6th month of pregnancy.

Warnings and precautions

Talk to your doctor or pharmacist before taking Seractil, if

- you ever have had a stomach or duodenal ulcer;
- you have had bowel ulcers, ulcerative colitis or Crohn's disease;
- you have liver or kidney disease or you are addicted to alcohol;
- you have blood clotting disorders (also see the 'Taking other medicines' section);
- you have oedema (when fluid collects in your body tissues);
- you have a heart disease or high blood pressure;
- you have asthma or any other breathing problems;
- you suffer from systemic lupus erythematosus (a disease which affects joints, muscles and skin) or mixed connective tissue disease (a collagen disease which affects connective tissues).

Seractil may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant. Your fertility will return to normal when you stop taking Seractil.

If you need higher doses, especially if you are over 60 or if you had stomach or duodenal ulcers, there is an increased risk of gastrointestinal side effects. Your doctor may consider to prescribe protective agents together with Seractil.

Medicines such as Seractil may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Your doctor may need to give you regular check-ups if:

- you have heart, liver or kidney problems;
 - you are older than 60;
 - you need to take this medicine for long-term treatment.
- Your doctor will tell you how often you need these check-ups.

You can get a headache if you take high doses of painkillers for a long time (off label use). In this case you must not take more Seractil for the headache.

You should avoid taking NSAIDs if you have a varicella zoster infection (chickenpox).

Some patients might experience a delayed onset of action if Seractil is taken for a quick pain relief in acute pain conditions, especially if taken with food (see also section 3).

Other medicines and Seractil

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should **not** take the following medicines with Seractil unless you are under close medical supervision:

- Non-steroidal anti-inflammatory drugs (medicines for pain, fever and inflammation). There is an increased risk of ulcers and bleedings in the digestive system if you take Seractil with other NSAIDs or acetylsalicylic acid (aspirin). Do not take if you are taking aspirin at doses of above 75 mg daily.
- Warfarin or other medicines used to thin the blood or stop blood clots. If you take this medicine with Seractil it can prolong bleeding time or bleeding can occur.
- Lithium used to treat certain mood disorders. Seractil can increase the effect of lithium.
- Methotrexate. Seractil can increase the side effects of methotrexate.

You **may** take the following medicines but for safety reasons you should tell your doctor:

- Medicines used to treat high blood pressure or heart problems (for example, beta blockers). Seractil may reduce the benefits of these medicines.
- Certain heart medicines called ACE-inhibitors or Angiotensin II receptor antagonists. They may increase the risk of kidney problems in rare cases.
- Diuretics (water tablets).
- Corticosteroids. The risk for ulcers and bleeding may increase.
- Certain antidepressants (selective serotonin reuptake inhibitors) may increase the risk for gastro intestinal bleeding.
- Digoxin (a heart medicine). Seractil can increase the side effects of digoxin.
- Immune suppressants like ciclosporin.
- Aminoglycoside antibiotics (medicines to treat infections)
- Medicines that increase potassium levels in the blood: ACE inhibitors, angiotensin-II receptor antagonists, ciclosporin, tacrolimus, trimethoprim and heparins.
- Drugs used to stop or prevent blood clots. Seractil may make your body take longer to stop bleeding.
- Phenytoin used to treat epilepsy. Seractil may increase the side effects of phenytoin.
- Phenytoin, phenobarbital and rifampicin. Concomitant administration may lower the effects of dexibuprofen.
- Low dose aspirin (up to 75 mg). Seractil may interfere with the effect of aspirin to thin the blood.
- Sulfonylurea (certain oral anti-diabetic medicines)
- Pemetrexed (a medicine to treat certain forms of cancer)
- Zidovudine (a medicine to treat HIV/AIDS)

Seractil with food, drink and alcohol

You may take Seractil without food, but it is better to take it with a meal as this may help to avoid stomach problems, particularly if you take it for long term use.

You should limit or avoid drinking alcohol when you are taking Seractil as this may increase gastrointestinal side effects.

Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

You must not take Seractil from the beginning of the 6th month of pregnancy, as this may seriously harm your unborn baby, even at very low doses.

In the first five months of pregnancy you should only use Seractil after consulting your doctor.

You also should not take Seractil if you plan to become pregnant, as the medicine may make it more difficult to become pregnant.

Only small amounts of Seractil pass into breast milk. However, if you are breast-feeding, you should not take Seractil for long periods or in high doses.

Driving and using machines

If you have side effects like feeling dizzy, drowsy, tired, or if you have blurred vision after taking Seractil, you should avoid driving or using any dangerous machines (see section 4 Possible side effects).

3. How to take Seractil

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

You should take Seractil with a glass of water or some other liquid. Seractil works faster if you take it without food. Taking it with food is recommended as this may help to avoid stomach problems, particularly if you take it for long term use.

Do not take more than **1** Seractil 400mg tablet for a **single dose**. Do not take more than **3** Seractil 400mg tablets **a day**.

For osteoarthritis

The recommended dose is 1 Seractil 400mg tablet 2 times a day (1 in the morning and 1 in the evening). For acute symptoms, your doctor may increase the dose to 3 Seractil 400mg tablets a day.

For period (menstrual) pain

The recommended dose is 1 Seractil 400mg tablet 2 times a day.

For mild to moderate pain

The recommended dose is 200 mg Seractil (half a 400 mg tablet) 3 times a day. If higher doses are needed your doctor may prescribe up to 3 Seractil 400mg tablets a day. Depending on your symptoms, the doctor may also prescribe lower strength Seractil tablets (300 mg).

The score lines on the tablets (see the 'What Seractil looks like' section) make it possible for you to split the tablets into equal doses.

Patients with liver or kidney disease: Your doctor may have prescribed a lower than the normal dose of Seractil. You must not increase the dose your doctor has prescribed.

Elderly patients: If you are over 60 years old, your doctor may have prescribed a lower dose than normal. If you are not having problems taking Seractil, your doctor may increase your dose.

Use in children and adolescents: As there is not enough experience in children and adolescents Seractil should not be used below the age of 18.

If you feel that the effects of your Seractil tablets are too strong or too weak, talk to your doctor or pharmacist.

If you take more Seractil than you should

If you have accidentally taken too many tablets, contact your doctor straight away.

If you forget to take Seractil

Do not take a double dose to make up for a forgotten tablet.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

These do not happen as often when you take a low dose or you take Seractil for only a short time.

If you suffer from any of the following at any time during your treatment **stop taking** the medicine and seek **immediate medical help**:

- Pass blood in your faeces (stools/motions)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds.

Stop taking the medicine and **tell your doctor** if you experience indigestion or heartburn, abdominal pain (pains in your stomach) or other abnormal stomach symptoms.

Also stop taking Seractil and see a doctor,

- if you have a skin rash, severe blistering or peeling of the skin, mucosal lesions or any signs of hypersensitivity.
- if you have symptoms like fever, sore throat and mouth, flu like symptoms, feeling tired, nose and skin bleed. These can be caused by a reduction of white blood cells in your body (agranulocytosis).
- if you have severe or persistent headache.
- if you have a yellow coloration of the skin and the whites of the eyes (jaundice).
- if you have a swollen face, tongue or pharynx, difficulty to swallow or to breathe (angioedema).

The most frequent side effects are of gastrointestinal nature like indigestion, stomach ache, diarrhoea, being sick or feeling sick. Some gastrointestinal side effects can be serious, although they do not affect many people, like ulcers and bleeding in the stomach or intestines and perforations in the digestive system (for symptoms see "stop taking Seractil and see a doctor" above).

Other side effects are:

Common: affect 1 to 10 users in 100.

- feeling exhausted or drowsy, dizziness, headaches;
- a skin rash.

Uncommon: affect 1 to 10 users in 1000.

- ulcers in the mouth, gastritis;
- purpura (purple bruises), itching, a raised itchy rash;
- swelling of the face or throat (angioedema);
- problems with sleeping, restlessness, anxiety, blurred vision, buzzing or ringing in the ears (tinnitus);
- runny nose, difficulties breathing.

Rare: affect 1 to 10 users in 10000.

- a strong allergic reaction;
- psychotic reactions, depression, feeling irritable;
- feeling confused, disoriented or agitated;
- hearing problems;
- wind, constipation, an inflamed oesophagus, flare up of diverticular disease (small pouches in your bowels that may become infected or inflamed), colitis or Crohn's disease;
- problems with your liver, hepatitis (inflamed liver) and jaundice (yellowing of the skin or eyes);
- blood disorders, including disorders that reduce the number of white or red blood cells or platelets.

Very rare: affect less than 1 user in 10000.

- hypersensitivity reactions, including symptoms like fever, a rash, pain in the abdomen, headaches, feeling sick and vomiting;
- photosensitivity;
- aseptic meningitis (symptoms are headache, fever, stiff neck and generally feeling ill), serious allergic reactions (difficulty breathing, asthma, a fast heartbeat, low blood pressure and shock), allergic reaction with inflamed small blood vessels;
- reddened skin, mucous membranes or throat;
- blistering hands and feet (Stevens-Johnson syndrome);
- peeling skin (epidermal necrolysis);
- hair loss;
- inflamed kidney, kidney disease or kidney failure;
- systemic lupus erythematosus (auto immune disease);
- very rare bacterial infections, which attack the tissue covering the muscle can be aggravated.

Oedema (swollen limbs), high blood pressure and heart failure may occur with NSAID treatment.

Medicines such as Seractil may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. How to store Seractil

Do not store above 25°C.

Keep out of the sight and reach of children.

Protect from light.

Store in the original package.

Don't take the tablets after the "expiry date" shown on the pack. If your tablets are out of date, take them to your pharmacist who will get rid of them safely. Any unused medication should be returned to a pharmacy for disposal.

If your tablets appear discoloured or show any other signs of deterioration, take them to your pharmacist who will advise you. 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 to protect the environment.

6. Contents of the pack and other information

What Seractil contains

Each film coated tablet contains 400mg of the active ingredient, dexibuprofen.

Your tablets also include the following ingredients: hypromellose, microcrystalline cellulose, carmellose calcium, colloidal anhydrous silica, talc, titanium dioxide (E171), glycerol triacetate and macrogol 6000.

What Seractil looks like, and the contents of the pack

Each tablet is white, oblong and scored on both sides.

Seractil tablets are packed in blister strips and are available in packs of 10, 30, 50 and 60 tablets.

Manufacturer

Your tablets are manufactured by: Gebro Pharma GmbH, Fieberbrunn, Austria.

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR.

Product Licence holder: BR Lewis Pharmaceuticals Ltd., Kirk Sandall, Doncaster, DN3 1QR.

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Dexibuprofen 400mg film-coated Tablets

Your medicine is available using the name Dexibuprofen 400mg film-coated Tablets but will be referred to as Dexibuprofen throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any more questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.*
- *If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.*

What is in this leaflet

1. What Dexibuprofen is and what it is used for
2. What you need to know before you take Dexibuprofen
3. How to take Dexibuprofen
4. Possible side effects
5. How to store Dexibuprofen
6. Contents of the pack and other information

1. What Dexibuprofen is and what it is used for

Dexibuprofen, the active ingredient in Dexibuprofen, belongs to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs such as dexibuprofen are used as a painkiller and to control inflammation. They work by reducing the amount of prostaglandins (substances that control inflammation and pain) your body produces.

What is Dexibuprofen used for?

Dexibuprofen is used to relieve:

- pain and inflammation caused by osteoarthritis (when your joints become worn);
- period (menstrual) pain;
- mild to moderate pain, such as pains in the muscles and joints and toothaches.

2. What you need to know before you take Dexibuprofen

Do not take Dexibuprofen if:

- you are allergic to dexibuprofen or any of the other ingredients of this medicine (listed in section 6);
- you are allergic to acetylsalicylic acid or other pain-killers (your allergy may cause you to have difficulty breathing, asthma, a runny nose, a skin rash or swelling to your face);
- you previously had bleedings or perforations in your gastrointestinal system caused by NSAIDs;
- you have, or have ever had, peptic ulceration (ulcer in your stomach or duodenum) or bleeding in your digestive tract;
- you have bleedings in the brain (cerebrovascular bleedings) or other active bleedings;
- you currently have a flare up of an inflammatory disease of the intestines (ulcerative colitis, Crohn's disease);
- you have serious heart failure or serious liver or kidney disease;
- from the beginning of the 6th month of pregnancy.

Warnings and precautions

Talk to your doctor or pharmacist before taking Dexibuprofen, if

- you ever have had a stomach or duodenal ulcer;
- you have had bowel ulcers, ulcerative colitis or Crohn's disease;
- you have liver or kidney disease or you are addicted to alcohol;
- you have blood clotting disorders (also see the 'Taking other medicines' section);
- you have oedema (when fluid collects in your body tissues);
- you have a heart disease or high blood pressure;
- you have asthma or any other breathing problems;
- you suffer from systemic lupus erythematosus (a disease which affects joints, muscles and skin) or mixed collagenosis (a collagen disease which affects connective tissues).

Dexibuprofen may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant. Your fertility will return to normal when you stop taking Dexibuprofen.

If you need higher doses, especially if you are over 60 or if you had stomach or duodenal ulcers, there is an increased risk of gastrointestinal side effects. Your doctor may consider to prescribe protective agents together with Dexibuprofen.

Medicines such as Dexibuprofen may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Your doctor may need to give you regular check-ups if:

- you have heart, liver or kidney problems;
- you are older than 60;
- you need to take this medicine for long-term treatment.

Your doctor will tell you how often you need these check-ups.

You can get a headache if you take high doses of painkillers for a long time (off label use). In this case you must not take more Dexibuprofen for the headache.

You should avoid taking NSAIDs if you have a varicella zoster infection (chickenpox).

Some patients might experience a delayed onset of action if Dexibuprofen is taken for a quick pain relief in acute pain conditions, especially if taken with food (see also section 3).

Other medicines and Dexibuprofen

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should **not** take the following medicines with Dexibuprofen unless you are under close medical supervision:

- Non-steroidal anti-inflammatory drugs (medicines for pain, fever and inflammation). There is an increased risk of ulcers and bleedings in the digestive system if you take Dexibuprofen with other NSAIDs or acetylsalicylic acid (aspirin). Do not take if you are taking aspirin at doses of above 75 mg daily.
- Warfarin or other medicines used to thin the blood or stop blood clots. If you take this medicine with Dexibuprofen it can prolong bleeding time or bleeding can occur.
- Lithium used to treat certain mood disorders. Dexibuprofen can increase the effect of lithium.
- Methotrexate. Dexibuprofen can increase the side effects of methotrexate.

You **may** take the following medicines but for safety reasons you should tell your doctor:

- Medicines used to treat high blood pressure or heart problems (for example, beta blockers). Dexibuprofen may reduce the benefits of these medicines.
- Certain heart medicines called ACE-inhibitors or Angiotensin II receptor antagonists. They may increase the risk of kidney problems in rare cases.
- Diuretics (water tablets).
- Corticosteroids. The risk for ulcers and bleeding may increase.
- Certain antidepressants (selective serotonin reuptake inhibitors) may increase the risk for gastro intestinal bleeding.
- Digoxin (a heart medicine). Dexibuprofen can increase the side effects of digoxin.
- Immune suppressants like ciclosporin.
- Aminoglycoside antibiotics (medicines to treat infections)
- Medicines that increase potassium levels in the blood: ACE inhibitors, angiotensin-II receptor antagonists, ciclosporin, tacrolimus, trimethoprim and heparins.
- Drugs used to stop or prevent blood clots. Dexibuprofen may make your body take longer to stop bleeding.
- Phenytoin used to treat epilepsy. Dexibuprofen may increase the side effects of phenytoin.
- Phenytoin, phenobarbital and rifampicin. Concomitant administration may lower the effects of dexibuprofen.
- Low dose aspirin (up to 75 mg). Dexibuprofen may interfere with the effect of aspirin to thin the blood.
- Sulfonylurea (certain oral anti-diabetic medicines)
- Pemetrexed (a medicine to treat certain forms of cancer)
- Zidovudine (a medicine to treat HIV/AIDS)

Dexibuprofen with food, drink and alcohol

You may take Dexibuprofen without food, but it is better to take it with a meal as this may help to avoid stomach problems, particularly if you take it for long term use. You should limit or avoid drinking alcohol when you are taking Dexibuprofen as this may increase gastrointestinal side effects.

Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

You must not take Dexibuprofen from the beginning of the 6th month of pregnancy, as this may seriously harm your unborn baby, even at very low doses.

In the first five months of pregnancy you should only use Dexibuprofen after consulting your doctor.

You also should not take Dexibuprofen if you plan to become pregnant, as the medicine may make it more difficult to become pregnant.

Only small amounts of Dexibuprofen pass into breast milk. However, if you are breast-feeding, you should not take Dexibuprofen for long periods or in high doses.

Driving and using machines

If you have side effects like feeling dizzy, drowsy, tired, or if you have blurred vision after taking Dexibuprofen, you should avoid driving or using any dangerous machines (see section 4 Possible side effects).

3. How to take Dexibuprofen

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

You should take Dexibuprofen with a glass of water or some other liquid. Dexibuprofen works faster if you take it without food. Taking it with food is recommended as this may help to avoid stomach problems, particularly if you take it for long term use.

Do not take more than **1** Dexibuprofen 400mg tablet for a **single dose**.

Do not take more than **3** Dexibuprofen 400mg tablets a **day**.

For osteoarthritis

The recommended dose is 1 Dexibuprofen 400mg tablet 2 times a day (1 in the morning and 1 in the evening). For acute symptoms, your doctor may increase the dose to 3 Dexibuprofen 400mg tablets a day.

For period (menstrual) pain

The recommended dose is 1 Dexibuprofen 400mg tablet 2 times a day.

For mild to moderate pain

The recommended dose is 200 mg Dexibuprofen (half a 400 mg tablet) 3 times a day. If higher doses are needed your doctor may prescribe up to 3 Dexibuprofen 400mg tablets a day. Depending on your symptoms, the doctor may also prescribe lower strength Dexibuprofen tablets (300 mg).

The score lines on the tablets (see the 'What Dexibuprofen looks like' section) make it possible for you to split the tablets into equal doses.

Patients with liver or kidney disease: Your doctor may have prescribed a lower than the normal dose of Dexibuprofen. You must not increase the dose your doctor has prescribed.

Elderly patients: If you are over 60 years old, your doctor may have prescribed a lower dose than normal. If you are not having problems taking Dexibuprofen, your doctor may increase your dose.

Use in children and adolescents: As there is not enough experience in children and adolescents Dexibuprofen should not be used below the age of 18.

If you feel that the effects of your Dexibuprofen tablets are too strong or too weak, talk to your doctor or pharmacist.

If you take more Dexibuprofen than you should

If you have accidentally taken too many tablets, contact your doctor straight away.

If you forget to take Dexibuprofen

Do not take a double dose to make up for a forgotten tablet.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. These do not happen as often when you take a low dose or you take Dexibuprofen for only a short time.

If you suffer from any of the following at any time during your treatment **stop taking** the medicine and seek **immediate medical help**:

- Pass blood in your faeces (stools/motions)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds.

Stop taking the medicine and **tell your doctor** if you experience indigestion or heartburn, abdominal pain (pains in your stomach) or other abnormal stomach symptoms.

Also stop taking Dexibuprofen and see a doctor,

- if you have a skin rash, severe blistering or peeling of the skin, mucosal lesions or any signs of hypersensitivity.
- if you have symptoms like fever, sore throat and mouth, flu like symptoms, feeling tired, nose and skin bleed. These can be caused by a reduction of white blood cells in your body (agranulocytosis).
- if you have severe or persistent headache.
- if you have a yellow coloration of the skin and the whites of the eyes (jaundice).
- if you have a swollen face, tongue or pharynx, difficulty to swallow or to breathe (angioedema).

The most frequent side effects are of gastrointestinal nature like indigestion, stomach ache, diarrhoea, being sick or feeling sick. Some gastrointestinal side effects can be serious, although they do not affect many people, like ulcers and bleeding in the stomach or intestines and perforations in the digestive system (for symptoms see "stop taking Dexibuprofen and see a doctor" above).

Other side effects are:**Common:** affect 1 to 10 users in 100.

- feeling exhausted or drowsy, dizziness, headaches;
- a skin rash.

Uncommon: affect 1 to 10 users in 1000.

- ulcers in the mouth, gastritis;
- purpura (purple bruises), itching, a raised itchy rash;
- swelling of the face or throat (angioedema);
- problems with sleeping, restlessness, anxiety, blurred vision, buzzing or ringing in the ears (tinnitus);
- runny nose, difficulties breathing.

Rare: affect 1 to 10 users in 10000.

- a strong allergic reaction;
- psychotic reactions, depression, feeling irritable;
- feeling confused, disoriented or agitated;
- hearing problems;
- wind, constipation, an inflamed oesophagus, flare up of diverticular disease (small pouches in your bowels that may become infected or inflamed), colitis or Crohn's disease;
- problems with your liver, hepatitis (inflamed liver) and jaundice (yellowing of the skin or eyes);
- blood disorders, including disorders that reduce the number of white or red blood cells or platelets.

Very rare: affect less than 1 user in 10000.

- hypersensitivity reactions, including symptoms like fever, a rash, pain in the abdomen, headaches, feeling sick and vomiting;
- photosensitivity;
- aseptic meningitis (symptoms are headache, fever, stiff neck and generally feeling ill), serious allergic reactions (difficulty breathing, asthma, a fast heartbeat, low blood pressure and shock), allergic reaction with inflamed small blood vessels;
- reddened skin, mucous membranes or throat;
- blistering hands and feet (Stevens-Johnson syndrome);
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Oedema (swollen limbs), high blood pressure and heart failure may occur with NSAID treatment.

Medicines such as Dexibuprofen may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. How to store Dexibuprofen

Do not store above 25°C.

Keep out of the sight and reach of children.

Protect from light.

Store in the original package.

Don't take the tablets after the "expiry date" shown on the pack.

If your tablets are out of date, take them to your pharmacist who will get rid of them safely. Any unused medication should be returned to a pharmacy for disposal.

If your tablets appear discoloured or show any other signs of deterioration, take them to your pharmacist who will advise you. 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 to protect the environment.

6. Contents of the pack and other information**What Dexibuprofen contains**

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Your tablets also include the following ingredients: hypromellose, microcrystalline cellulose, carmellose calcium, colloidal anhydrous silica, talc, titanium dioxide (E171), glycerol triacetate and macrogol 6000.

What Dexibuprofen looks like, and the contents of the pack

Each tablet is white, oblong and scored on both sides.

Dexibuprofen tablets are packed in blister strips and are available in packs of 10, 30, 50 and 60 tablets.

Manufacturer

Your tablets are manufactured by: Gebro Pharma GmbH, Fieberbrunn, Austria.

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, DN3 1QR.

Product Licence holder: BR Lewis Pharmaceuticals Ltd., Kirk Sandall, Doncaster, DN3 1QR.

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