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FRONT

Solpadeine® MAX Tablets

Paracetamol, Codeine

- This medicine is for the short term treatment of acute moderate pain when other painkillers have not worked.
- You should only take this product for a **maximum of 3 days** at a time. If you need to take it for longer than 3 days you should **see your doctor or pharmacist** for advice.
- This medicine **contains codeine** which can **cause addiction** if you take it continuously for **more than 3 days**. This can give you **withdrawal symptoms** from the medicine when you stop taking it.
- If you take this medicine for headaches for **more than 3 days** it can **make them worse.**

Please read right through this leaflet before you start using this medicine.
This medicine is available without prescription, but you still need to use Solpadeine Max Tablets carefully to get the best results from them.

- Keep this leaflet you may need to read it again.
- If you have any questions, or if there is anything you do not understand, ask your pharmacist.

In this leaflet:

1. What Solpadeine Max Tablets do
2. Check before you take Solpadeine Max Tablets
3. How to take Solpadeine Max Tablets
4. Possible side effects
5. How to store Solpadeine Max Tablets
6. Further information

1. What Solpadeine Max Tablets do

Solpadeine Max Tablets are for the **short term treatment of acute moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone.** They can be used for migraine, headache, dental pain, period pain, strains & sprains, backache, arthritic & rheumatic pain and sciatica.
The tablets contain two active ingredients. Paracetamol and codeine are painkillers. By working on your body in different ways, they combine to relieve pain.

2. Check before you take Solpadeine Max Tablets

- This medicine **contains codeine** which can **cause addiction** if you take it continuously for **more than 3 days**. This can give you **withdrawal symptoms** from the medicine when you stop taking it.
- If you take a painkiller for headaches for **more than 3 days** it can **make them worse**.

Do not take Solpadeine Max Tablets:

- **If you have ever had an allergic reaction** to paracetamol, codeine, other opioid painkillers or to any of the other ingredients (listed in Section 6)
- If you are **taking other medicines containing paracetamol** or **codeine.**

Ask your doctor before you take this medicine:

- If you have **liver** or **kidney disease**, including **alcoholic liver disease**
- If you have **bowel problems** including blockage of your bowel
- If you have had an **operation to remove your gall bladder**
- If you have been told by your doctor that you have an **intolerance to some sugars**.

If you are taking other medicines

Talk to your doctor or pharmacist before taking these tablets if you are taking any prescribed medicines; particularly **metoclopramide** or **domperidone** (for **nausea** [feeling sick] or **vomiting** [being sick]); **colestyramine** (to lower **blood cholesterol**); **monoamine oxidase inhibitors** (MAOIs prescribed for **depression**) or medicines that make you **drowsy**. If you take **blood thinning drugs** (**anticoagulants** e.g. **warfarin**) and you need to take a pain reliever on a daily basis, **talk to your doctor** because of the risk of bleeding. But you can still take **occasional** doses of Solpadeine Max Tablets at the same time as anticoagulants.

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Pregnancy and breast feeding

Talk to your doctor before taking Solpadeine Max Tablets if you are **pregnant. Do not use whilst breast feeding** unless advised by your doctor.

3. How to take Solpadeine Max Tablets

Adults and children aged 12 years and over:
Swallow 2 tablets every 4 hours as needed.

- Do not take more frequently than **every 4 hours.**
- Do not take more than **8 tablets in 24 hours.**
- Do not take **more than the recommended dose.**
- Do not give to children **under 12 years.**
- Do not take for more than **3 days.** If you need to use this medicine for more than **3 days** you **must speak** to your doctor or pharmacist.

Possible withdrawal effects

This medicine **contains codeine** and can **cause addiction** if you take it continuously for **more than 3 days**. When you stop taking it you may get **withdrawal symptoms**. You should **talk to your doctor or pharmacist** if you think you are suffering from withdrawal symptoms.

If you take too many tablets

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

If your symptoms continue or your headache becomes persistent, **see your doctor**.

4. Possible side effects

Some people may have side effects when using this medicine. If you have any unwanted side effects you should seek advice from your doctor, pharmacist or other healthcare professional. Also you can help make sure that medicines remain as safe as possible by **reporting any unwanted side effects** via the internet at **www.yellowcard.gov.uk**; alternatively you can **call Freephone** 0808 100 3352 (available between 10am-2pm Monday - Friday) or fill in a **paper form** available from your local pharmacy.

When using this product you may experience:

- Constipation.

Stop taking this medicine and **tell your doctor immediately** if you experience:

- Severe **abdominal pain, nausea** and **vomiting** if you have recently had your gall bladder removed
- **Allergic reactions** which may be severe such as skin rash and itching sometimes with swelling of the mouth or face or shortness of breath
- **Skin rash or peeling** or **mouth ulcers**
- **Breathing problems.** These are more likely if you have experienced them before when taking other painkillers such as ibuprofen and aspirin
- Unexplained **bruising** or **bleeding**
- **Nausea,** sudden **weight loss, loss of appetite** and **yellowing of the eyes and skin.**

If you do get any side effects, even those not mentioned in this leaflet, tell your doctor or pharmacist.

How do I know if I am addicted?

If you take this medicine according to the instructions on the pack, it is unlikely you will become addicted to the medicine. However, if the following apply to you it is important that you **talk to your doctor**:

- You need to take the medicine for **longer periods of time.**
- You need to take **more than the recommended dose.**
- When you stop taking the medicine you feel very unwell but you **feel better if you start taking the medicine again.**

5. How to store Solpadeine Max Tablets

Keep out of the reach and sight of children.
Do not use this medicine after the 'EXP' date shown on the pack.

6. Further information

Active ingredients Each tablet contains Paracetamol 500 mg and Codeine Phosphate Hemihydrate 12.8 mg.
Other ingredients Starch pregelatinised, povidone, potassium sorbate (E 202), maize starch, talc, magnesium stearate, stearic acid, microcrystalline cellulose, croscarmellose sodium, lactose monohydrate, hypromellose, macrogol, quinoline yellow (E 104), erythrosine (E 127) and titanium dioxide (E 171).

Packs of Solpadeine Max Tablets contain 20 or 30 tablets.

The marketing authorisation holder is Omega Pharma Ltd, 32 Vauxhall Bridge Road, London, SW1V 2SA, United Kingdom and all enquiries should be sent to this address.
The manufacturer is GlaxoSmithKline Dungarvan Ltd., Co. Waterford, Ireland or Omega Pharma Manufacturing GmbH & Co. KG, Benzstraße 25, 71083, Herrenberg, Germany or SmithKline Beecham S.A. Carretera de Ajalvir Km 2,500, Alcala de Henares, 28806 Madrid, Spain.

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