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RIGHT HAND BAR

LEFT HAND BAR

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Solpadeine® HEADACHE

TABLETS ***Paracetamol, Caffeine***

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
This medicine is available without prescription, but you still need to use Solpadeine Headache Tablets carefully to get the best results from them.
- Keep this leaflet, you may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

In this leaflet:

1. What Solpadeine Headache Tablets are and what they are used for
2. What you need to know before you take Solpadeine Headache Tablets
3. How to take Solpadeine Headache Tablets
4. Possible side effects
5. How to store Solpadeine Headache Tablets
6. Contents of the pack and other information

1. What Solpadeine Headache Tablets are and what they are used for

Solpadeine Headache Tablets can provide effective relief from headache including migraine. They can also relieve backache, rheumatic and muscle pain, toothache, sore throat, period pain and relieve the fever, aches and pains of colds and flu.
The tablets contain two active ingredients. Paracetamol is a painkiller and also reduces your temperature when you have a fever. Caffeine acts to further help the effectiveness of paracetamol.

2. What you need to know before you take Solpadeine Headache Tablets

Do not take Solpadeine Headache Tablets:

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

Ask your doctor before you take this medicine:

- If you have **liver** or **kidney disease, including alcoholic liver disease**
- If you suffer from **hepatocellular insufficiency**
- If you have **chronic alcoholism**
- If you have **Gilbert's Syndrome** (familial non-haemolytic jaundice)
- **If you are taking other medicines that can affect the liver**
- If you have **glucose-6-phosphate dehydrogenase deficiency**
- If you have **haemolytic anaemia**
- If you have **glutathione deficiency**
- If you are **dehydrated**

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BACK

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- If you have had **poor diet** such that the diet causes health problems
- If you **weigh less than 50kg**

They may reduce the dose or increase the time interval between doses of your medicine

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]) or **colestyramine** (to lower **blood cholesterol**); medicines that make you **drowsy or sedated** (e.g. **barbiturates** such as; **phenobarbitone, tricyclic antidepressants, alcohol, carbamazepine, phenytoin, primidone, rifampicin, St John's Wort**). If you take **blood thinning drugs** (**anticoagulants** e.g. **warfarin and other coumarins**) 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 Headache Tablets at the same time as anticoagulants. If you take medicine to treat **gout and hyperuricemia** (e.g. **probenecid**). If you are malnourished and taking medicine to treat bacterial infections (e.g. **chloramphenicol**). Please inform your doctor or pharmacist if you are taking **flucloxacillin (antibiotic)**, due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

Pregnancy, breast feeding and fertility

Due to the caffeine content of this product **it should not be used** if you are **pregnant** or **breast feeding.** There is no available data on the influence of this product on fertility.

Driving and using machines

Solpadeine Headache Tablets has no or negligible influence on the ability to drive and use machines.

This medicine contains less than 1 mmol sodium (23 mg) per 2 tablets, that is to say essentially 'sodium-free'.

3. How to take Solpadeine Headache Tablets

Adults and adolescents aged 16 years and over:
Swallow 2 tablets every 4-6 hours as needed.

- Do not take more frequently than every 4 hours.
- Do not take more than 8 tablets in 24 hours.

Adolescents aged 12 – 15 years:
Swallow 1 tablet every 4-6 hours as needed.

- Do not take more frequently than every 4 hours.
- Do not take more than 4 tablets in 24 hours.

- **Do not take more than the recommended dose.**
- **Do not give to children under 12 years.**
- **Avoid too much caffeine in drinks like coffee and tea.**

High caffeine intake can cause **difficulty sleeping, shaking and an uncomfortable feeling in the chest.**

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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

Like all medicines, Solpadeine Headache Tablets can have side effects, although not everybody gets them.
Stop taking the medicine and **tell your doctor immediately** if you experience:
- **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.**
- **Cloudy urine** or **difficulties urinating**

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

5. How to store Solpadeine Headache Tablets

Keep out of the reach and sight of children. Do not use this medicine after the 'EXP' date shown on the pack. Store below 25°C.

6. Contents of the pack and other information

Active ingredients: Each tablet contains Paracetamol 500 mg and Caffeine 65 mg.
Other ingredients: Starch pregelatinised, maize starch, polyvinyl pyrrolidone, potassium sorbate (E 202), purified talc, stearic acid, croscarmellose sodium, hypromellose and triacetin.

Packs of Solpadeine Headache Tablets contain 16 tablets.

The marketing authorisation holder is
Omega Pharma Ltd., Wrafton, Braunton, Devon, EX33 2DL,
United Kingdom and all enquiries should be sent to this address.

The manufacturer is GlaxoSmithKline Dungarvan Ltd., Co. Waterford, Ireland.

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