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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

X 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
- 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

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During treatment with Solpadeine Headache Tablets, tell your doctor straight away if you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

! 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 (called metabolic acidosis) that must have urgent treatment (see section 2).

! 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

Frequency "Not known" (frequency cannot be estimated from the available data): A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

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.

This leaflet was last revised in February 2025.

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Brand:	Application:	Perrigo component code:	Supplier component code:	Market:	Component size (flat):	Barcode 1 type:	-
Solpadeine	Tablets	LF23422F	N/A only for submission	UK	210 x140 mm	Barcode 1 nr:	-
Variant:	Size:	Component type:	Languages on component:	AMS Project nr:	Techn. drawing ref:	Barcode 2 type:	-
Headache	16	Leaflet	English	Program002693	-	Barcode 2 nr:	-
	1: Black	5: -	9: -	Manufacturer:	Folded size:	Pharma code:	UDI code:
	2: -	6: -	Cutter	GSK Dungarvan	-	-	-
	3: -	7: -	Substrate:	Printer:	Specification/reel unwind ref:	Serialization code:	Approval date
	4: -	8: -	-	-	-	-	-
Pass nr:	Pass date:	Pass nr:	Pass date:	Pass nr:	Pass date:	Pass nr:	Pass date:
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							Leaflet_1028