

Package leaflet: Information for the patient

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

1. What Hedex Extra do and what it is used for

Hedex Extra can provide extra 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 Hedex Extra

Do not take Hedex Extra:

- 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

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 Hedex Extra 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

Hedex 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 Hedex Extra

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.**

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, Hedex Extra 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 Hedex Extra

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. Further 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 Hedex Extra 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 2023