

Package Leaflet: Information for the user

DYPRACET 20mg/500mg tablets

DYPRACET 30mg/500mg tablets

Dihydrocodeine Tartrate Paracetamol

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 further 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. 4.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

- This medicine contains paracetamol.
- Do not take any other paracetamol containing products.
- Do not exceed the stated dose.
- Immediate medical advice should be sought in the event of overdosage because of the risk of irreversible liver damage

What is in this leaflet:

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1. What DYPRACET Tablets are and what they are used for

The name of this medicine is DYPRACET 20 mg/500 mg & DYPRACET 30 mg/500 mg Tablets. These tablets have been prescribed for you to relieve severe pain over a period of 4 to 6 hours. They contain the active ingredients dihydrocodeine tartrate and paracetamol which belong to a group of medicines called strong analgesics or 'painkillers'. The other ingredients are listed in section 6 of this leaflet.

2. What you need to know before you take DYPRACET Tablets

Do not take DYPRACET Tablets if you:

- Are allergic to dihydrocodeine, paracetamol or any of the other ingredients of this medicine (listed in section 6);
- Have breathing problems, such as breathing more slowly or weakly than expected, or obstructive airways disease;
- Are having an asthma attack.
- Children **under 12 years of age** should not take these tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking your DYPRACET Tablets if you suffer from any of the following:

- Have asthma or any allergies;
- Have an under-active thyroid gland (hypothyroidism);
- Have kidney or long-term liver problems;
- Have a severe headache or feel sick due to a head injury or increased pressure in your skull (for instance due to brain disease). This is because the tablets may make these symptoms worse or hide the extent of a head injury;
- Have prostate problems;
- Are addicted to alcohol;
- Are or have ever been addicted to drugs.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking this medicine.

Other medicines and DYPRACET Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Taking some medicines together can be harmful.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Any other medicines containing paracetamol (you should not take these tablets if you are already taking another medicine containing paracetamol);
- Medicines to help you sleep (for example tranquillisers, hypnotics or sedatives);
- Medicines to treat psychiatric or mental disorders;
- A type of medicine known as a monoamine oxidase inhibitor (examples include tranylcypromide, phenelzine, isocarboxazid, moclobamide and linezolid), or you have taken this type of medicine in the last two weeks;
- Medicines to treat depression or anxiety;
- Metoclopramide or domperidone to stop you feeling or being sick;
- Cholestyramine to treat high blood pressure or diarrhoea;
- Medicines such as warfarin to prevent your blood clotting or to help thin your blood. If you are unsure of the types of medicines you are taking, ask your doctor or pharmacist.

DYPRACET Tablets with alcohol

Drinking alcohol during your treatment with these tablets may make you sleepy. If you are affected you should avoid drinking alcohol.

Pregnancy and breast feeding

If you are pregnant or breastfeeding do not take these tablets until you have spoken to your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

You may feel sleepy when taking these tablets. If you are affected you should not drive or use machinery.

3. How to take DYPRACET Tablets

Two different strengths of tablets are available. Your doctor will decide which strength of tablet will suit you best.

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

DYPRACET Tablets should be taken orally. The tablets should be swallowed whole with a glass of water.

Do not take these tablets if you are already taking another medicine containing paracetamol.

Adults:

The recommended starting dose for adults over 18 years of age is one or two tablets every 4 to 6 hours.

Your doctor will prescribe the dose required to treat your pain. If you find that you are still in pain whilst taking these tablets discuss this with your doctor.

Do not take more than eight tablets in 24 hours.

Adolescents 16-18 years:

The recommended starting dose for adolescents aged between 16 and 18 years is **one or two tablets** every 6 hours as needed.

Do not take more than eight tablets in 24 hours.

Children 12-15 years:

The recommended starting dose for children aged between 12 and 15 years is **one tablet** every 6 hours as needed.

Do not take more than four tablets in 24 hours.

Your doctor will prescribe the dose required to treat your pain. If you find that you are still in pain whilst taking these tablets discuss this with your doctor.

Elderly

If you are elderly your doctor may suggest a lower starting dose.

Children under 12 years of age:

This product should not be taken by children under 12 years of age.

If you take more DYPRACET Tablets than you should

Call your doctor or hospital straight away. People who have taken an overdose may feel very sleepy and sick, and have abdominal pain. They may also have breathing difficulties leading to unconsciousness or even death and may need emergency treatment in hospital. You should contact your doctor immediately even if you feel well as there is a risk of serious liver damage.

When seeking medical attention make sure that you take this leaflet and any remaining tablets with you to show the doctor.

If you forget to take DYPRACET Tablets

If you miss a dose you should take it as soon as you remember and then carry on as before. Do not take a double dose to make up for a forgotten tablet.

If you stop taking DYPRACET Tablets

You should not stop taking these tablets unless your doctor tells you to. If you want to stop taking your tablets, discuss this with your doctor first.

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.

Contact your doctor immediately if you experience any sudden wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body as these may indicate an allergy to the product

Other side effects**Common side effects (may affect up to 1 in 10 people)**

- Most people will have constipation when they take these tablets. Your doctor can prescribe a laxative to overcome this problem.
- You may feel sick or vomit (be sick) when you take your tablets, this should normally wear off after a few days however your doctor can prescribe an anti-vomiting medicine if it continues to be a problem.
- You may find that you feel more sleepy than normal when you start taking your tablets or when your dose is increased. This should wear off after a few days.
- Headache and a rash or itchy skin have also been commonly reported in patients treated with these tablets.

Uncommon side effects (may affect up to 1 in 100 people)

- An unpleasant or uncomfortable mood.
- Hallucinations.
- A feeling of dizziness or 'spinning'.
- Difficulty in passing urine.
- A need to take increasingly higher doses to obtain the same level of pain relief (tolerance).
- Withdrawal symptoms such as agitation, anxiety, shaking or sweating upon stopping taking the tablets.

Rare side effects (may affect up to 1 in 1,000 people)

- Inflammation of the pancreas (which causes severe pain in the abdomen and back).
- Abnormal cells in the blood (blood dyscrasias).

As with all strong painkillers, there is a risk you may become addicted or reliant on these tablets.

Taking a painkiller for headaches too often or for too long can make your headaches worse.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAPharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store DYPRACET Tablets

Keep this medicine out of the sight and reach of children.

There are no special storage instructions for DYPRACET Tablets.

Do not use this medicine after the expiry date which is stated on the carton, blister and pot container. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What DYPRACET Tablets contains

The active substances are paracetamol and dihydrocodeine tartrate.

- Each Dypracet 20 mg/500 mg Tablet contains paracetamol 500 mg and dihydrocodeine tartrate 20 mg.
- Each Dypracet 30 mg/500 mg Tablet contains paracetamol 500 mg and dihydrocodeine tartrate 30 mg.

The other ingredients are microcrystalline cellulose, povidone K30, colloidal anhydrous silica and magnesium stearate.

What DYPRACET looks like and contents of the pack

DYPRACET 20 mg/500 mg Tablets are oblong, white tablets, 19 mm x 7 mm long with the marking 'P500 D20' on one side.

DYPRACET 30 mg/500 mg Tablets are oblong, white tablets, 19 mm x 7 mm long with the marking 'P500 D30' on one side.

DYPRACET 20 mg/500 mg Tablets are available in pots of 56 or 112 tablets and blisters of 56 or 112 tablets.

DYPRACET 30 mg/500 mg Tablets are available in pots of 56 tablets and blisters of 56 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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