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.
- 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.

The name of your medicine is Dipipanone/Cyclizine 10mg/30mg Tablets. It will be referred to as Dipipanone/Cyclizine Tablets for ease hereafter.

What is this leaflet about?

1. What Dipipanone/Cyclizine Tablets are and what they are used for

Dipipanone/Cyclizine Tablets contain the active ingredients dipipanone hydrochloride and cyclizine hydrochloride. Dipipanone hydrochloride belongs to a group of medicines called opioid analgesics and is used for pain relief. Cyclizine hydrochloride belongs to a group of medicines called anti-emetics which reduce nausea and vomiting that may occur. Dipipanone/Cyclizine Tablets are used to relieve moderate to severe pain and nausea in certain medical or surgical situations.

2. What you need to know before you take Dipipanone/Cyclizine Tablets

Do not take Dipipanone/Cyclizine Tablets:

- If you are allergic to dipipanone hydrochloride, cyclizine hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- If you have allergic reactions which include rashes, swollen lips/face or difficulty breathing.
- If you have a history of head injury.
- If you have previously been dependent on opioid painkillers or other similar substances.
- If you are a man with an enlarged prostate gland.
- If you have kidney problems.
- If you have liver problems.
- If you have diabetes.
- If you have had an allergic reaction to this medicine in the past.
- If you are taking, or have recently taken (within the last 14 days) a medicine from a group of medicines called monoamine oxidase inhibitors (MAOIs) and are for pain relief. Cyclizine hydrochloride belongs to a group of medicines called anti-emetics which reduce nausea and vomiting that may occur. Dipipanone/Cyclizine Tablets are used to relieve moderate to severe pain and nausea in certain medical or surgical situations.

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- If you have liver problems.
- If you have diabetes.
- If you have had an allergic reaction to this medicine in the past.
3. HOW TO TAKE DIPIPANONE/CYCLIZINE TABLETS

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

Swallow your tablets whole with water.

Your doctor may change your dose depending on your response and how severe your pain is. Do not exceed the recommended dose.

Dosage:
The recommended dosage for adults is one tablet taken every 6 hours.

Tell your doctor immediately. These may be signs of an allergic reaction.

• if you are taking more Dipipanone/Cyclizine Tablets than you should, contact your doctor or nearest hospital emergency department immediately. Take the container and any remaining tablets with you.

If you forget to take Dipipanone/Cyclizine Tablets
If you forget to take a dose, just take the next dose at the usual time, DO NOT take a double dose.

If you stop taking Dipipanone/Cyclizine Tablets suddenly you may experience:

• double dose.

If you forget to take a dose, just take the next dose at the usual time, DO NOT take a double dose.

If you stop taking Dipipanone/Cyclizine Tablets suddenly you may experience withdrawal symptoms.

Withdrawal symptoms include:

• sweating, muscle tremor, weakness, abdominal cramps, constipation, depression, an increase in white blood cells, bone pain, stomach pain and cramps, “goose pimples”, increased heart rate, blood pressure and temperature.

4. POSSIBLE SIDE EFFECTS

Like all medicines this medicine can cause side effects, although not everybody gets them.

If you notice:

• itching or skin rash;
• swelling of the face, lips or throat;
• difficulty in breathing or wheeziness.

Tell your doctor immediately. These may be signs of an allergic reaction.

Tell your doctor as soon as possible, if you experience the following:

• feeling very tired, experience unexpected bruising or bleeding, or more infections (e.g. colds and sore throats) than usual please tell your doctor as soon as possible, your doctor may decide to conduct tests on your blood periodically as a result of these symptoms.

• if you notice:
• abdominal pain/spasm could be due to condition known as biliary obstruction;
• fatigue, nausea, loss of appetite, or yellow skin or eyes could be due to infection of the liver (hepatitis);
• abdominal pain or cramps, “goose pimples”, increased heart rate, breathing rate, blood pressure and temperature.

The following side effects are reported with a not known frequency:

• abdominal pain, diarrhoea, dehydration, an increase in white blood cells, bone pain, stomach pain and cramps, “goose pimples”, increased heart rate, breathing rate, blood pressure and temperature.

Do not exceed the recommended dose.

If you forget to take a dose, just take the next dose at the usual time, DO NOT take a double dose.

If you stop taking Dipipanone/Cyclizine Tablets suddenly you may experience:

• double dose.

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• sweating, muscle tremor, weakness, abdominal cramps, constipation, depression, an increase in white blood cells, bone pain, stomach pain and cramps, “goose pimples”, increased heart rate, blood pressure and temperature.

The following side effects are reported with a not known frequency:

• headaches;
• indigestion;
• diarrhoea;
• constipation;
• dizziness, light-headedness or vertigo;
• low blood pressure/shaking, coma;
• high blood pressure;
• increased blood pressure within the head;
• swelling of the ankles, feet or fingers;
• increased heart rate;
• slow or irregular heart beat;
• palpitations;
• tinnitus;
• palpitation;
• low blood pressure/fainting, coma;
• abdominal pain;
• constriction of the pupils (small pupils);
• blurred vision;
• injected veins.

Some people may become tolerant of, or addicted to, this medicine when treatment continues for a long time.

5. HOW TO STORE DIPIPANONE/CYCLIZINE TABLETS

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

Do not use this medicine after the expiry date which is stated on the foil and carton after EXP. The expiry date refers to the last day of that month. Store in a dry, safe place below 25°C. Store in the original package in order to protect from light.

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 Dipipanone/Cyclizine Tablets contain

The active substances are dipipanone hydrochloride 10 mg and cyclizine hydrochloride 30 mg. The other ingredients are lactose, starches, crospovidone (E407), gelatin and magnesium stearate.

What Dipipanone/Cyclizine Tablets look like and contents of the pack

Dipipanone/Cyclizine Tablets are deep pink in colour, scored, coated FIA and are supplied in blister packs containing 50 tablets.

Marketing Authorisation Holder and Manufacturer responsible for release:
Amdipharm UK Limited,
Capital House, 10 King-William Street, London EC1N 7BL, UK
This leaflet was last revised in June 2010.

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