

Package leaflet: Information for the patient

Dipipanone/Cyclizine 10mg/30mg Tablets

Dipipanone hydrochloride 10 mg and Cyclizine hydrochloride 30 mg

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 in this leaflet

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

This medicine contains dipipanone which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

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. This medicine has been prescribed for you for pain relief. It contains the dipipanone which belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been prescribed to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely. Cyclizine hydrochloride belongs to a group of medicines called anti-emetics which reduce any 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 mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing
- if you have any **lung disease** (such as bronchitis), difficulty in breathing, or have excessive phlegm
- if you suffer from any obstructive airway disease
- if you are having an **asthma attack**
- suffer from heart failure as a result of chronic lung disease
- if you are addicted to, or often drink large amounts of alcohol
- if you have recently suffered any **head injury** or have been told that you have raised pressure around your brain
- if you are taking, or have recently taken (within the last 14 days) a medicine from a group of **anti depressants** called monoamine oxidase inhibitors (MAOIs)
- if you have a **bowel disorder** such as ulcerative colitis
- if you are at risk of paralytic ileus (a condition where there is inactivity or paralysis within the bowel which stops the passage of material within the intestine)
- if you suffer from abdominal pain/ spasm (spasms of the biliary tract and/or renal tract). Do not take Dipipanone/Cyclizine Tablets immediately after having abdominal surgery (biliary tract surgery)
- if you are about to undergo surgery or have had surgery within the past 24 hours
- if you have severe liver or kidney problems.

Warnings and precautions

Talk to your doctor or pharmacist before taking Dipipanone/Cyclizine Tablets if you:

- are in a weakened or debilitated state
- suffer from involuntary muscle movement (convulsive disorders)
- have any problems with your thyroid, adrenal or pituitary glands
- are a man with an enlarged prostate gland
- are suffering from shock
- have diabetes
- suffer from an immune disorder characterised by muscle weakness (myasthenia gravis)
- have low blood pressure due to loss of blood or fluids
- suffer from pancreatitis (which can cause severe pain in the abdomen or back)
- suffer from an obstructive disease affecting the stomach and intestines
- suffer from an inflammatory bowel disorder
- have a disease affecting the series of passageways that carry bile into the intestines
- have difficulty breathing (impaired respiratory function)
- have difficulty passing urine (urinary retention)
- have severe heart failure
- have been told you have a rare condition called porphyria (a blood disease)
- suffer from an eye disease caused by a rise of pressure within the eye (glaucoma)
- have a tumour of the adrenal gland (phaeochromocytoma).

Talk to your prescriber before taking this medicine if you:

- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more of Dipipanone/Cyclizine tablets to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else.

Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

If any of these apply to you, or if you are not sure, tell your doctor before taking Dipipanone/Cyclizine Tablets.

Other medicines and Dipipanone/Cyclizine Tablets

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

This is especially important if you are taking:

- medicines for problems such as depression, anxiety or psychosis, or are taking a sedative (usually to treat insomnia)
- gabapentin (to treat epilepsy or nerve pain)
- medicines used to relieve high blood pressure
- muscle relaxants
- pethidine (used in the treatment of pain)
- mexiletine (used in the treatment of heart rhythm disorders)
- metoclopramide (used in the treatment of nausea and vomiting)
- monoamine oxidase inhibitors (see section 'Do not take...')
- cimetidine (used in the treatment of heartburn and ulcers)

- any medicines which belong to a group of medicines called anticholinergic medicines. This may be for Parkinson's disease, asthma etc. Check with your doctor if you are not sure
- aminoglycoside antibiotics, such as gentamicin (used in the treatment of infections)
- a medicine called dexamphetamine (used to treat narcolepsy or attention deficit disorder)
- diuretics (used to promote urine production)
- hydroxyzine (used to relieve anxiety caused by some mental disorders)
- propranolol (used in the treatment of high blood pressure or anxiety)
- St John's Wort (a herbal medication used in the treatment of depression)
- ritonavir (used in the treatment of HIV and AIDS).

Dipipanone/Cyclizine Tablets may also interfere with some laboratory tests performed by your doctor.

Dipipanone/Cyclizine Tablets with food, drink and alcohol

Do not drink alcohol while taking Dipipanone/Cyclizine Tablets, as the tablets can increase the effects of alcohol.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine.

Pregnancy

Do not take Dipipanone/Cyclizine tablets if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use Dipipanone/Cyclizine tablets during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Breastfeeding

Do not take Dipipanone/Cyclizine tablets while you are breastfeeding as dipipanone passes into breast milk and will affect your baby.

Driving and using machines

Dipipanone/Cyclizine Tablets may make you feel dizzy or drowsy. If they affect you in this way, **do not** drive or operate any machinery.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- do not drive while taking this medicine until you know how it affects you
- it is an offence to drive if this medicine affects your ability to drive
- however, you would not be committing an offence if:
 - the medicine has been prescribed to treat a medical or dental problem and
 - you have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - it was not affecting your ability to drive safely.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Dipipanone/Cyclizine Tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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.

Your prescriber should have discussed with you, how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

Adults

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

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.

Treatment with Dipipanone/Cyclizine Tablets should not be withdrawn suddenly, particularly if the medicine has been used by the patient for a long time. The use of the drug should be gradually withdrawn to avoid unnecessary side effects.

Use in children

Dipipanone/Cyclizine Tablets are rarely used in children. No guidelines can be given on the recommended dose for children.

Elderly

Dipipanone/Cyclizine Tablets may cause confusion in this age group. Careful monitoring is advised.

If you take more Dipipanone/Cyclizine Tablets than you should

Symptoms of overdose include difficulty breathing, slower or faster heartbeat, pin point pupils, low blood pressure, drowsiness, dry mouth, nose and throat, blurred vision, difficulty passing urine, dizziness, lack of balance and coordination, weakness, excitability, disorientation, impaired judgment, hallucinations, muscle spasms, involuntary movements, fits, and high temperature. If you take 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

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as yawning, dilated pupils, tears, a runny nose, sneezing, muscle tremors, weakness, anxiety, irritability, agitation, feeling your heartbeat (palpitations), increased blood pressure, difficulty sleeping, shaking, restlessness, decreased appetite, weight loss, feeling or being sick, 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, shivering or sweating may occur if you suddenly stop taking this medicine.

4. Possible side effects

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

If you notice:

- itching or skin rashes;
- 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
- inflammation of the pancreas which causes severe pain in the abdomen and back
- decreased consciousness
- experiencing a loss of contact with reality
- fits
- loss of coordination or unusual body movements, particularly of the hands, arms or legs
- fatigue, nausea, loss of appetite, or yellow skin or eyes could be due to inflammation of the liver (hepatitis)
- abdominal pain/spasm could be due to condition known as biliary pain/spasm.

The following side effects are reported with:

Uncommon (may affect up to 1 in 100 people)

Drug Withdrawal

When you stop taking Dipipanone/Cyclizine Tablets, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

Not known frequency (frequency cannot be estimated from the available data):

- a dry mouth, nose or throat
- sweating
- feeling of weakness
- generally feeling unwell
- feeling cold
- headaches
- facial flushing
- dizziness, light-headedness or vertigo
- low blood pressure/fainting, coma
- high blood pressure
- increased blood pressure within the head
- swelling of the ankles, feet or fingers
- increase in heart rate
- slow or irregular heart beat
- palpitations
- nervousness or restlessness, agitation, confusion and mood changes
- uncomfortable mood or feeling of happiness
- seeing or hearing things that are not really there (hallucinations)
- ringing in the ears
- breathing difficulties such as wheezing
- a decreased cough reflex
- itching or nettle rash
- sensitivity to light
- abdominal pain
- constriction of the pupils (small pupils)
- blurred vision
- involuntary rolling of the eyes
- visual disturbances
- feeling sick and being sick
- constipation
- acid reflux
- diarrhoea
- loss of appetite
- indigestion
- taste disturbances
- difficulty or pain in passing water
- difficulty in sleeping
- tiredness or drowsiness;
- muscle twitches, spasms or tremors
- a tingling/burning sensation of the skin
- jaundice (yellowing of the skin and whites of the eyes)
- blood tests which show changes in the way the liver is working
- difficulty in speaking
- changes in blood counts which may:
 - make infections more likely, or
 - make the skin pale and cause weakness or breathlessness, or

increase the risk of bleeding or bruising

- decreased sex drive
- erectile dysfunction (in men)
- absence of menstrual periods (in women).
- dependence and addiction (see section “How do I know if I am addicted?”).
- unpleasant sensation or an overwhelming urge to move the legs (also called Restless Legs Syndrome).

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

How do I know if I am addicted?

If you notice any of the following signs whilst taking Dipipanone/Cyclizine tablets, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber

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 the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

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 contains

The active substances are dipipanone hydrochloride 10 mg and cyclizine hydrochloride 30 mg. The other ingredients are lactose, starches, erythrosine (E127), gelatin and magnesium stearate.

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

Dipipanone/Cyclizine Tablets are deep pink in colour, scored, coded F3A and are supplied in blister packs containing 50 tablets.

Marketing Authorisation Holder:

Amdipharm UK Limited,
Dashwood House,
69 Old Broad Street, London,
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Manufacturer

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