Package leaflet: Information for the patient
Dipipanone/Cyclizine 10mg/30mg Tablets

Dipipanone hydrochloride 10 mg and Cyclizine hydrochloride 30 mg

1. WHAT DIPIPANONE/CYCLIZINE TABLETS ARE AND WHAT THEY ARE USED FOR

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

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DIPIPANONE/CYCLIZINE

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 allergy reactions which include rash symptoms such as itching and/or rash. More serious 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 asthmatic attack
- if you have 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 an 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 medicines called opioid analgesics and is used for pain relief. 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.

3. HOW TO TAKE DIPIPANONE/CYCLIZINE TABLETS

- 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.

4. POSSIBLE SIDE EFFECTS

- This medicine may cause side effects, which usually disappear when the treatment is stopped.
- Rare side effects may include:
- dizziness
- sleepiness
- constipation
- dry mouth
- increased appetite
- nausea
- headache
- unusual tiredness
- skin rash
- skin itching
- unusual bleeding
- unusual bruising

5. DRIVING AND USING MACHINES

- It is advised that you do not drive while taking this medicine or operate any machinery.
- However, if you do drive while taking this medicine and you find that it affects you, you should stop taking this medicine and consult your doctor.

6. PREGNANCY AND BREAST-FEEDING

- If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine.
- You should not breast-feed whilst you are taking Dipipanone/Cyclizine Tablets.

7. OTHER MEDICATIONS AND DIPIPANONE/CYCLIZINE TABLETS

- Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.
- It 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 pain or nerve pain)
  - medicines used to refine high blood pressure
  - muscle relaxants
  - pethidine (used in the treatment of pain)
  - medicines used in the treatment of heart rhythm disorders
  - metoprolol (used in the treatment of heart disease and angina)
  - medicines used to relieve high blood pressure (such as diuretics and co-enzymes)
  - medicines used to treat cancer (such as chemotherapy and radiosensitive medicines. This may be for Parkinson’s disease, asthma etc. Check with your doctor if you are not sure
  - any medicines which belong to a group of medicines called anticholinergic medicines. These include: antihistamines, such as from an eye disease caused by a rise of pressure within the eye (glaucoma)
  - have severe heart failure
  - have had a heart attack
  - have been told you have a rare condition called porphyria, i.e. 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). Dippipanone/Cyclizine Tablets may also interfere with some laboratory tests performed by your doctor.

8. DISPOSITION OF DIPIPANONE/CYCLIZINE TABLETS

- Do not take mislabeled Dippipanone/Cyclizine Tablets.

9. ADDITIONAL INFORMATION

- If you feel you are not getting any benefit from this medicine or you are not sure, talk to your pharmacist.
- If you have been told by your doctor that you have an intolerance to some sugars, Dipipanone/Cyclizine Tablets contain lactose.

10. WHAT IF YOU SUSPECT AN ALLERGIC REACTION TO DIPIPANONE/CYCLIZINE TABLETS

- Consult your doctor or pharmacist if you are not sure whether it is safe for you.

11. OVERDOSE

- In the unlikely event of an overdose, seek medical advice immediately and take the label with you.

12. PATIENT INFORMATION LEAFLET

- This leaflet is designed to help you understand your medicine. It is not a substitute for advice from your doctor or pharmacist.

13. ADDITIONAL INFORMATION

- This leaflet has been written for patients to give you a general idea of how to take Dipipanone/Cyclizine Tablets, it has not been written for health professionals.

14. ABILITY TO CONSENT

- It is important that you are able to consent for surgery, to be able to give informed consent. The person taking care of you should explain the risks of the procedure to you.

15. REPRODUCTION

- If you have any questions or concerns about the use of this medicine, please consult your doctor or pharmacist.

16. PACKAGE CONTENTS

- You should keep all medicines out of the reach of children.

17. DIPIPANONE/CYCLIZINE TABLETS

- The active ingredients in Dippipanone/Cyclizine Tablets are 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 any nausea and vomiting that may occur.

18. DIPIPANONE/CYCLIZINE TABLETS

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

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20. DIPIPANONE/CYCLIZINE TABLETS

- 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.

21. DIPIPANONE/CYCLIZINE TABLETS

- This medicine may cause side effects, which usually disappear when the treatment is stopped.
- Rare side effects may include:
- dizziness
- sleepiness
- constipation
- dry mouth
- increased appetite
- nausea
- headache
- unusual tiredness
- skin rash
- skin itching
- unusual bleeding
- unusual bruising

22. DIPIPANONE/CYCLIZINE TABLETS

- It is advised that you do not drive while taking this medicine or operate any machinery.
- However, if you do drive while taking this medicine and you find that it affects you, you should stop taking this medicine and consult your doctor.

23. DIPIPANONE/CYCLIZINE TABLETS

- If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine.
- You should not breast-feed whilst you are taking Dipipanone/Cyclizine Tablets.

24. DIPIPANONE/CYCLIZINE TABLETS

- Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.
- It 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 pain or nerve pain)
  - medicines used to refine high blood pressure
  - muscle relaxants
  - pethidine (used in the treatment of pain)
  - medicines used in the treatment of heart rhythm disorders
  - metoprolol (used in the treatment of heart disease and angina)
  - medicines used to relieve high blood pressure (such as diuretics and co-enzymes)
  - 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
  - any medicines which belong to a group of medicines called anticholinergic medicines. These include: antihistamines, such as from an eye disease caused by a rise of pressure within the eye (glaucoma)
  - have severe heart failure
  - have had a heart attack
  - have been told you have a rare condition called porphyria, i.e. 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). Dippipanone/Cyclizine Tablets may also interfere with some laboratory tests performed by your doctor.

25. DIPIPANONE/CYCLIZINE TABLETS

- Do not take mislabeled Dippipanone/Cyclizine Tablets.

26. DIPIPANONE/CYCLIZINE TABLETS

- If you feel you are not getting any benefit from this medicine or you are not sure, talk to your pharmacist.
- If you have been told by your doctor that you have an intolerance to some sugars, Dipipanone/Cyclizine Tablets contain lactose.

27. DIPIPANONE/CYCLIZINE TABLETS

- This leaflet is designed to help you understand your medicine. It is not a substitute for advice from your doctor or pharmacist.

28. DIPIPANONE/CYCLIZINE TABLETS

- It is important that you are able to consent for surgery, to be able to give informed consent. The person taking care of you should explain the risks of the procedure to you.

29. DIPIPANONE/CYCLIZINE TABLETS

- If you have any questions or concerns about the use of this medicine, please consult your doctor or pharmacist.

30. DIPIPANONE/CYCLIZINE TABLETS

- You should keep all medicines out of the reach of children.
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.

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.

Older people

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 heart beat, pin point pupils, low blood pressure, drowsiness, dry mouth, nose and throat, blurred vision, difficulty passing urine, dizziness, lack of balance and coordination, weakness, irritability, 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

If you stop taking Dipipanone/Cyclizine Tablets suddenly you may experience withdrawal symptoms. Withdrawal symptoms include: yawning, dilated pupils, tear, a runny nose, sneezing, muscle tremors, weakness, sweating, anxiety, irritability, disturbed sleep or nightmares, confusion, agitation, and panic attacks. The symptoms listed above are normal and tend to subside as the body eliminates the drug.

4. POSSIBLE SIDE EFFECTS

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

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 or skin rashes;
- swelling of the face, lips or throat;
- difficulty in breathing or wheeziness;

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

If you notice:

- itching or skin rashes;
- swelling of the face, lips or throat;
- difficulty in breathing or wheeziness;

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

Tell your doctor as soon as possible. If you experience the following:

- feeling very tired, experience unexplained bruising or bleeding, or more infections (e.g. colds and sore throat) 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;
- It is possible that you may have:
- 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 or discomfort could be due to conditions known as biliary tract disease;
- the following side effects are reported with a not known frequency (frequency cannot be estimated from the available data);
- the side effects of Dipipanone/Cyclizine Tablets may include:
- 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/lightheaded, 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;
- nervousness, or restlessness, agitation, confusion and mood changes;
- uncontrolled 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 rashes rash;
- sensitivity to light;
- abdominal pain;
- construction of the pupils (small pupils);
- blurred vision;
- involuntary rolling of the eyes;
- visual disturbances;
- itching or skin rashes;
- constipation;
- acid reflux;
- diarrhoea;
- loss of appetite;
- impotence;
- taste disturbances;
- difficulty or pain in passing water;
- difficulty in sleeping;
- tiredness or drowsiness;
- muscle twitching, tremors or tremor;
- a frequent or frequent sensation of the skin;
- paroxysm (the feeling of the skin and veins 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);
- Some people may become tolerant of, or addicted to, this medicine when treatment continues for a long time.

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 contain

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, coated F3A and are supplied in blister packs containing 50 tablets.

Marketing Authorisation Holder and Manufacturer:

Amdipharm UK Limited, Capital House, DD King Street, London EC1R 7BL, UK

Manufacturer

Camen - 52 Rue Marcel ET Jacques, Gaultier, Fontenuy-Gosse-Bre, F-94120, France

This leaflet was last revised in October 2018.