Package Leaflet: Information for the user

Kemadrin 5 mg Tablets
procyclidine hydrochloride

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.

What is in this leaflet

1. What Kemadrin is and what it is used for
2. What you need to know before you take Kemadrin
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1. What Kemadrin is and what it is used for

Kemadrin contains a medicine called procyclidine. This belongs to a group of medicines called anticholinergics. They stop a substance called acetylcholine working in your body.

You must talk to a doctor if you do not feel better or if you feel worse.

Kemadrin is used to:
- treat and relieve the signs of Parkinson's disease such as:
  - stiff muscles, paralysis, and tremor (shaking of hands)
  - problems talking, writing and walking
  - producing too much saliva and dribbling
  - sweating and uncontrolled eye movements
  - depression
- stop side effects called 'extrapyramidal effects', which are caused by some medicines. These may include signs similar to Parkinson's disease or restlessness and unusual head and body movements.

2. What you need to know before you take Kemadrin

Do not take Kemadrin if:
- you are allergic to procyclidine or any of the other ingredients of this medicine (listed in section 6).
- you experience uncontrolled movements of the head or tongue (tardive dyskinesia)

Do not take if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Kemadrin.

Warnings and precautions
Talk to your doctor or pharmacist before taking Kemadrin:
- if you are elderly. Your dose may need to be carefully monitored to prevent any side effects
- if you suffer from a problem caused by too much pressure in your eye called 'narrow angle glaucoma' or if you have a higher chance to get glaucoma
- if you have constipation
- if you have problems passing water (urinary retention)
- if you have an enlarged prostate gland
- if you have a mental illness and are taking Kemadrin to control the side-effects of your medicines.
  Occasionally people who take this medicine may have a psychotic episode
- if you have kidney or liver problems
- if you have an obstructive disease of the stomach or bowels (e.g. pyloric stenosis, paralytic ileus)
- if you have any underlying condition that causes your heart to beat faster (e.g. thyroxicosis)
- in some patients who use Kemadrin to control side effects of other medicines, involuntary repetitive body movements may occur. If this happens to you, your doctor may decide to give you lower doses.

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

Children
Do not give this medicine to children.

Other medicines and Kemadrin
Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because Kemadrin can affect the way some other medicines work. Also some other medicines can affect the way Kemadrin works. In particular tell your doctor or pharmacist if you are taking any of the following:
- antidepressants, particularly those which contain monoamine oxidase inhibitors, including any taken in the past two weeks
- medicines used to treat mental health problems (including Alzheimer's disease and dementia)
- levodopa and amantadine, used in Parkinson's disease
- disopyramide, quinidine and nitrate tablets (including tablets that dissolve under the tongue), used to treat heart problems
- cisapride, domperidone and metoclopramide, used to treat sickness, indigestion and feeling sick (nausea)
- antihistamines, used to treat hayfever and allergies
- nefopam, used to treat pain
- paroxetine, used to treat depression and/or anxiety disorders in adults
- ketoconazole, used to treat fungal infections
- medicines such as phenothiazines used to treat psychoses - if you are taking this in combination with Kemadrin, you should be aware that going to a hot, humid climate may cause fever

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

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 or pharmacist for advice before taking this medicine.

Driving and using machines
You may have blurred vision, dizziness, confusion or disorientation while taking Kemadrin. If this happens do not drive or use any tools or machines.

Kemadrin contains 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.

Kemadrin contains sodium
Kemadrin contains less than 1 mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE KEMADRIN

Always take Kemadrin exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- Swallow the tablets with a drink of water.
- You can take Kemadrin at any time of day, with or without food. Some people find they feel less sick if they take it at meal times.
- The tablets may be cut or broken in half along the break-line to divide the dose in two equal halves.

To treat Parkinson's disease:
- The recommended starting dose is 2.5 mg (half a tablet) three times a day.
- This can be increased by 2.5 mg (half a tablet) each day, until your symptoms are under control.
  The usual maximum daily dose is 30 mg (6 tablets).
- The maximum your doctor may decide to prescribe is 12 tablets (60 mg).
- Although the dose is usually taken three times a day, your doctor may ask you to take a fourth dose before bedtime.

To treat uncontrolled body movements (extrapyramidal symptoms) caused by taking other medicines:
Kemadrin can be used to control side-effects caused by other medicines.
- The recommended starting dose is 2.5 mg (half a tablet) three times a day.
- This can be increased by 2.5 mg (half a tablet) each day until your symptoms are under control.
- The daily maintenance dose is usually not more than four tablets (20 mg).
- Your doctor may decide to stop your Kemadrin after three or four months to see if your original symptoms return.
- If you need Kemadrin for a longer period of time, your doctor may decide to stop every now and then.

Elderly
If you are elderly, your doctor will decide on the appropriate dose for you to take.

Use in children
Kemadrin tablets are not usually recommended for use in children.

If you take more Kemadrin than you should
If you take more Kemadrin than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Kemadrin
Take a dose as soon as you remember it and then go on as before. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Kemadrin
You should not stop taking Kemadrin without talking to your doctor first as your symptoms may return.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

The following side effects may happen with this medicine:

If you are taking a medicine for mental illness (called a neuroleptic) at the same time as Kemadrin:
- you can develop uncontrolled movements of your face and tongue (tardive dyskinesia). The dose of either of your medicines may need to be adjusted
- unusual body movements, particularly of your hands, arms and legs which may have previously been occurring with the medicine for your mental illness can be made worse by the addition of Kemadrin.

If either of these happen, tell your doctor straight away.

Common (affects less than 1 in 10 people)
- problems passing water (urinary retention)
- blurred vision
- dry mouth
- constipation.

Uncommon (affects less than 1 in 100 people)
- feeling sick (nausea) or being sick (vomiting)
- inflamed gums (gingivitis)
- dizziness, nervousness, feeling confused, not knowing where you are (feeling disoriented), difficulty in thinking, which may include problems with attention, reduced concentration or memory, hearing unexpected noises or seeing unexpected sights (hallucinations), anxiety, agitation (feeling irritable)
- skin rash.

Rare (affects less than 1 in 1,000 people)
- 'psychotic' symptoms occurring together such as dizziness, confusion, reduced concentration or memory, disorientation, hearing unexpected noises or seeing unexpected sights (hallucinations), anxiety, agitation (feeling irritable).

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

Ireland: HPRA Pharmacovigilance, Website: www.hpra.ie

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

5. HOW TO STORE KEMADRIN

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C.
- Do not use this medicine after the expiry date which is stated on the label and carton after "EXP".
  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 to protect the environment.

6. Contents of the pack and other information

What Kemadrin contains
- The active substance is procyclidine hydrochloride 5 mg.
- The other ingredients are lactose monohydrate, sodium carboxymethyl starch type A, povidone and magnesium stearate.

What Kemadrin looks like and contents of the pack
Kemadrin 5 mg Tablets are white, round, biconvex tablets, one face with a break-line and coded KT above the break-line and 05 below the break-line with a score-line on the other face. The tablets can be divided into equal doses.
Kemadrin 5 mg Tablets come in bottles of amber glass with snap-fit closure containing 100 tablets.

Parallel Product Authorisation holder
IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland.

Manufactured by
Aspen Bad Oldesloe GmbH, Industriestrasse 32-36, D-23843 Bad Oldesloe, Germany.

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