

Kemadrin® 5mg Tablets/ Procyclidine Hydrochloride 5mg Tablets

(procyclidine hydrochloride)

This product is available using any of the above names but will be referred to as Kemadrin throughout this:

Patient Information Leaflet

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. Do not pass it 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.

In this leaflet:

- 1) What Kemadrin is and what it is used for
- 2) What you need to know before you take Kemadrin
- 3) How to take Kemadrin
- 4) Possible side effects
- 5) How to store Kemadrin
- 6) Contents of the pack and other information

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.

Kemadrin is used to:

- treat and relieve the signs of Parkinson's disease such as:
 - stiff muscles, paralysis and tremor
 - 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 the 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 (hypersensitive) to procyclidine or any of the other ingredients of Kemadrin (see section 6)
 - you have problems passing water (urinary retention)
 - you suffer from a problem caused by too much pressure in your eye called 'closed angle glaucoma'
 - you have stomach cramps and pains or constipation.
- Do not take if any of 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 your medicine if:

- you are elderly. Your dose may need to be carefully monitored to prevent any side effects
- 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

- you have an obstructive disease of your bowel
 - you have an enlarged prostate gland
 - 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
 - you have kidney or liver problems
 - 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 apply 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, 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:

- 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
- ketoconazole, used to treat fungal infections.
- paroxetine

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

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant or are breast-feeding.

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 (a type of sugar).

If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.

3) How to take Kemadrin

Always take this medicine 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 tablet 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 half a tablet three times a day.
- This can be increased by half or one tablet each day, every two or three days until an effect is seen. This is known as the 'maintenance dose'. The daily maintenance dose is usually three to six tablets.
- The maximum your doctor may decide to prescribe is 12 tablets.
- 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 half a tablet three times a day.
- This can be increased by half a tablet each day until an effect is seen.
- The daily maintenance dose is usually two to six tablets.
- Your doctor may decide to stop your Kemadrin after three or four months to see if your side effects 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 dose may need to be carefully monitored to prevent any side effects.

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.

If you stop taking Kemadrin

Do not stop taking Kemadrin without talking to your doctor.

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 happens, 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), 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 disorder', which includes symptoms occurring together such as dizziness, confusion, reduced concentration or memory, disorientation, hearing unexpected noises or seeing unexpected sights (hallucinations), anxiety, agitation (feeling irritable).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5) How to store Kemadrin

- Keep out of the sight and reach of children
- Do not store above 25°C.
- Do not take this medicine after the expiry date stated on the carton or bottle label. The expiry date refers to the last day of that month.
- If your doctor tells you to stop taking your tablets, take any tablets you have left back to the pharmacy.
- If the tablets become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6) Contents of the pack and other information

What Kemadrin contains

Each tablet contains procyclidine hydrochloride 5mg as the active ingredient. Each tablet also contains lactose, sodium starch glycolate Type A, povidone and magnesium stearate.

What Kemadrin looks like and contents of the pack

Kemadrin tablets are White, biconvex tablets, one face with a break-line and marked 'KT' above the break-line and '05' below the break line, with the other side scored and devoid of additional markings.

They are available in bottles containing 100 tablets.

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Who makes and repackages your medicine?

Your medicine is manufactured by Aspen Bad Oldesloe GmbH, Industriestrasse 32-36, D-23843 Bad Oldesloe, Germany. Procured from within the EU and repackaged by the Product Licence Holder: Primecrown Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

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