KEMADRIN[™]

Procyclidine hydrochloride tablets 5mg

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start taking KEMADRIN tablets.

This leaflet answers some common questions about KEMADRIN tablets. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you taking KEMADRIN against the risks this medicine could have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What KEMADRIN is used for

KEMADRIN contains the active ingredient procyclidine.

KEMADRIN is used to treat and relieve the symptoms of Parkinson's disease. KEMADRIN is also used to manage the side effects of neuroleptic medicines (used to treat serious mental illnesses). These side effects are quite similar to the symptoms of Parkinson's disease.

Common parkinsonian symptoms include shaking of the head and limbs, muscle stiffness, an expressionless face and being unable to start and control muscle movements properly. These symptoms are caused by an imbalance between the chemicals dopamine and acetylcholine in the brain. These two chemicals normally work in a balanced way, transmitting nerve signals in the part of the brain controlling movement. In Parkinson's disease, the amount of dopamine in this part of the brain is reduced, so the effects of acetylcholine are stronger, and coordination of muscle movement is lost.

Dopamine levels in the brain are abnormally high in people with some mental illnesses, e.g. schizophrenia. Treatment with neuroleptic medication reduces these high levels, sometimes to below normal. If this happens, the balance between acetylcholine and dopamine in the brain gets out of balance causing parkinsonian-like symptoms.

KEMADRIN belongs to a group of medicines called anticholinergics. KEMADRIN works by stopping brain cell receptors from binding with acetylcholine, which helps to restore the balance with dopamine.

KEMADRIN is not a cure for Parkinson's disease but can relieve some of its symptoms, especially muscle stiffness, trembling and drooling. It is also helpful for speech and writing problems, shuffling while walking, sweating, mental depression and unusual eye movements.

Your doctor may have prescribed KEMADRIN for another reason.

Ask your doctor if you have any questions about why KEMADRIN has been prescribed for you.

KEMADRIN is available only with a doctor's prescription.

Before you take KEMADRIN

When you must not take it

Do not take KEMADRIN if:

You have had an allergic reaction before to procyclidine or to any of the ingredients in KEMADRIN listed at the end of this leaflet.

The packaging is torn or shows signs of interference, or the tablets look damaged or discoloured..

The expiry date on the packaging has passed. If you take this medicine after the expiry date has passed, it may not work as well. If the pharmacist has repacked the medicine for you, there may not be an expiry date on the pack.

Before you start using KEMADRIN

Tell your doctor if:

You are pregnant or plan to become pregnant.

It is not known if KEMADRIN is safe for an unborn baby when taken by a pregnant woman. You should avoid becoming pregnant while taking KEMADRIN.

If you are already pregnant, your doctor will weigh up the expected benefits of KEMADRIN to you against its possible risks to your unborn baby.

You are breastfeeding or planning to breastfeed. It is not known if procyclidine, the active ingredient in KEMADRIN, passes into breast milk, so mothers taking this medicine should not breastfeed.

You have (or have ever had) any other health problems, especially:

Glaucoma Mental illness Liver disease Kidney disease Prostate trouble Chronic constipation Problems with drug addiction

You are allergic to any other medicines, foods, dyes or preservatives.

If you have not told your doctor about any of the above, please do so before taking KEMADRIN.

Taking other medicines

Some medicines may affect the way others work.

Tell your doctor if you are taking any other medicines, including the oral contraceptive pill or medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

If you are taking any of the following medicines, please let your doctor know before taking KEMADRIN:

- Monoamine oxidase inhibitors, for mental depression
- Tricyclic antidepressants, for mental depression
- Paroxetine (AropaxTM) commonly used for mental depression and social disorders (anxiety, panic disorders etc)
- Phenothiazines for mental illness, commonly schizophrenia
- Neuroleptics for mental illness, commonly schizophrenia
- Antihistamines for allergic reactions
- Medicines used to treat gastric reflux and nausea such as cisapride (PrepulsidTM) and metoclopramide (ParamaxTM, MaxolonTM)
- Amantidine (SymmetrelTM), also used to control parkinsonian symptoms and to combat influenza
- Levodopa (MadoparTM, SinemetTM, SindopaTM) also used to control parkinsonian symptoms
- Quinidine (Kinidine[™]) for irregular heart rhythms

- Ketoconazole (NizoralTM) for fungal infections.
- Other agents with similar characteristics to KEMADRIN, such as tacrine.

Your doctor or pharmacist will be able to tell you more about what to do when taking KEMADRIN with other medicines.

Taking KEMADRIN

How much to take

Take KEMADRIN exactly as your doctor has prescribed.

Your doctor will tell you how many KEMADRIN tablets to take each day.

Your doctor may vary your dose of KEMADRIN to get the best balance between symptom control and side effects.

Never take more tablets than your doctor has prescribed.

In adults with Parkinson's disease, the usual starting dose is 2.5mg (half a tablet) three times daily. The dose is then increased by 2.5mg to 5mg daily every two to three days until symptoms are relieved. The usual long term dose needed to keep symptoms manageable is 15mg to 30mg daily. People who don't respond as well as expected to KEMADRIN alone can benefit from taking other medicines used to control symptoms of Parkinson's disease at the same time as KEMADRIN.

In adults with parkinsonian-like side effects from neuroleptic medication, the usual starting dose is 2.5mg three times daily, increased by 2.5mg each day until symptoms are under control. The effective long term dose is usually 10mg to 30mg daily. After three to four months, your doctor may want you to stop taking KEMADRIN for a while to see if you are still getting side effects from your neuroleptic medication.

KEMADRIN is not generally used in children. If it is prescribed for a child, the doctor will have weighed up the expected by nefits of KEMADRIN for the child against any possible risks.

The doses of KEMADRIN recommended for adults need to be reduced in elderly people who are more sensitive to this medicine and more likely to get side effects.

How to take it

Swallow tablets with a glass of water, preferably with food.

If you forget to take it

Do not take an extra dose. Wait until the next dose and take your normal dose then.

Do not try to make up for the dose that you missed by taking more than one dose at a time.

If you are not sure what to do, ask your doctor or pharmacist.

In case of an overdose

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else has taken too much KEMADRIN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep phone numbers for these places handy.

An overdose of KEMADRIN can cause agitation, restlessness, confusion, inability to sleep, mood changes, dilated pupils and a fast heart beat.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking KEMADRIN

Things you must do

Tell all doctors and pharmacists involved in your health care that you are taking KEMADRIN. Tell your doctor if you become pregnant while taking KEMADRIN.

Tell your doctor if, for any reason, you have not taken KEMADRIN exactly as prescribed. Otherwise, your doctor may think it is not working for you and change your medicine unnecessarily.

Tell your doctor if you feel that KEMADRIN is not helping your condition.

Things you must not do

Do not stop taking KEMADRIN or change the dose without first checking with your doctor, or your symptoms could return.

Do not give KEMADRIN to anyone else even if they appear to have the same condition as you.

Do not take any other medicines whether they require a prescription or not without first asking your doctor or a pharmacist.

Do not drive or operate machinery until you know how KEMADRIN is affecting you.

Side-Effects

All medicines can have unwanted side effects. Sometimes they may be serious, but often they are not. You may need medical treatment if you get some of the side effects. Ask your doctor or pharmacist to answer any questions you may have.

Be sure that your doctor or pharmacist knows as soon as possible if you do not feel well while you are taking KEMADRIN.

If you think that KEMADRIN is causing you to have an allergic (hypersensitivity) reaction, TELL YOUR DOCTOR IMMEDIATELY. Symptoms include:

- Severe skin rash, itching or hives
- Swelling of the face, lips, mouth or throat
- Difficulty breathing or swallowing
- Fever
- Low blood pressure (feeling faint or dizzy).

Tell your doctor if you notice any of the following:

- Dry mouth
- Blurredvision Constipation
- Difficulty passing urine
- Nausea (feeling as if you are about to vomit)
- Vomiting
- Red swollen gums Nervousness/anxiety/agitation Rash
- Dizziness
- Mental confusion, disorientation
- Problems with memory and understanding
- Hallucinations (seeing or
- hearing things that aren't real)
- Disordered thinking

Do not be alarmed by this list of side effects. Most of them are typical of anticholinergic medicines, and tend to occur only with higher doses of KEMADRIN.

Your doctor may recommend that you lower your dose of KEMADRIN if you get any of the above side effects.

This is not a complete list of all possible side effects with KEMADRIN.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not listed here.

Ask your doctor or pharmacist if you do not understand something on this list.

After taking it

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Keep KEMADRIN in a cool dry place away from light where the temperature stays below 25°C.

Do not store KEMADRIN or any other medicine in a bathroom or near a sink.

Do not leave it in a car or on a window sill.

Heat and dampness can destroy some medicines.

Keep KEMADRIN where young children cannot reach it.

A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking KEMADRIN, or the medicine has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What KEMADRIN looks like

KEMADRIN 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.

Ingredients

Procyclidine hydrochloride Lactose Sodium starch glycollate Povidone Magnesium stearate

Further information

Your doctor is the best person to give you advice on the treatment of your illness. You may also be able to find general information about its treatment from other sources, for example, books in public libraries and on the Internet.

Distributor

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