

Package leaflet: Information for the patient

Calmolan 0.26 mg prolonged-release tablets
Calmolan 0.52 mg prolonged-release tablets
Calmolan 1.05 mg prolonged-release tablets
Calmolan 1.57 mg prolonged-release tablets
Calmolan 2.1 mg prolonged-release tablets
Calmolan 2.62 mg prolonged-release tablets
Calmolan 3.15 mg prolonged-release tablets

Pramipexole

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

1. What Calmolan is and what it is used for

Calmolan contains the active substance pramipexole and belongs to a group of medicines known as dopamine agonists, which stimulate dopamine receptors in the brain. Stimulation of the dopamine receptors triggers nerve impulses in the brain that help to control body movements.

Calmolan is used to treat the symptoms of primary Parkinson's disease in adults. It can be used alone or in combination with levodopa (another medicine for Parkinson's disease).

2. What you need to know before you take Calmolan

Do not take Calmolan

if you are allergic to pramipexole or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before taking Calmolan. Tell your doctor if you have (had) or develop any medical conditions or symptoms, especially any of the following:

- Kidney disease.
- Hallucinations (seeing, hearing or feeling things that are not there). Most hallucinations are visual.
- Dyskinesia (e.g. abnormal, uncontrolled movements of the limbs). If you have advanced Parkinson's disease and are also taking levodopa, you might develop dyskinesia during the up titration of Calmolan.
- Dystonia (inability of keeping your body and neck straight and upright (axial dystonia)). In particular, you may experience forward flexion of the head and neck (also called antecollis),

forward bending of the lower back (also called camptocormia) or sideways bending of the back (also called pleurothotonus or Pisa syndrome). If this happens your doctor may want to change your medication.

- Sleepiness and episodes of suddenly falling asleep.
- Psychosis (e.g. comparable with symptoms of schizophrenia).
- Vision impairment. You should have regular eye examinations during treatment with Calmolan.
- Severe heart or blood vessels disease. You will need to have your blood pressure checked regularly, especially at the beginning of treatment. This is to avoid postural hypotension (a fall in blood pressure on standing up).

Tell your doctor if you or your family/carer notices that you are developing urges or cravings to behave in ways that are unusual for you and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These are called impulse control disorders and can include behaviours such as addictive gambling, excessive eating or spending, an abnormally high sex drive or preoccupation with an increase in sexual thoughts or feelings. Your doctor may need to adjust or stop your dose.

Tell your doctor if you or your family/carer notices that you are developing mania (agitation, feeling elated or over-excited) or delirium (decreased awareness, confusion, loss of reality). Your doctor may need to adjust or stop your dose.

Tell your doctor if you experience symptoms such as depression, apathy, anxiety, fatigue, sweating or pain after stopping or reducing your Calmolan treatment. If the problems persist more than a few weeks, your doctor may need to adjust your treatment.

Calmolan prolonged-release tablets is a specially designed tablet from which the active ingredient is gradually released, once the tablet has been ingested. Parts of tablets may occasionally be passed and seen in the stool (faeces) and may look like whole tablets. Inform your doctor if you find tablet pieces in your faeces.

Children and adolescents

Calmolan is not recommended for the use in children or adolescents under 18 years.

Other medicines and Calmolan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines, herbal remedies, health foods or supplements that you have obtained without a prescription.

You should avoid taking Calmolan together with antipsychotic medicines.

Take care if you are taking the following medicines:

- cimetidine (to treat excess stomach acid and stomach ulcers);
- amantadine (which can be used to treat Parkinson's disease);
- mexiletine (to treat irregular heartbeats, a condition known as ventricular arrhythmia);
- zidovudine (which can be used to treat the acquired immune deficiency syndrome (AIDS), a disease of the human immune system);
- cisplatin (to treat various types of cancers);
- quinine (which can be used for the prevention of painful night-time leg cramps and for the treatment of a type of malaria known as falciparum malaria (malignant malaria));
- procainamide (to treat irregular heart beat).

If you are taking levodopa, the dose of levodopa is recommended to be reduced when you start treatment with Calmolan.

Take care if you are using any medicines that calm you down (have a sedative effect) or if you are drinking alcohol. In these cases Calmolan may affect your ability to drive and operate machinery.

Calmolan with food and alcohol

You should be cautious while drinking alcohol during treatment with Calmolan.
Calmolan can be taken with or without food.

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. Your doctor will then discuss with you if you should continue to take Calmolan.

The effect of Calmolan on the unborn child is not known. Therefore, do not take Calmolan if you are pregnant unless your doctor tells you to do so.

Calmolan should not be used during breast-feeding. Calmolan can reduce the production of breast milk. Also, it can pass into the breast milk and can reach your baby. If use of Calmolan is unavoidable, breast-feeding should be stopped.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Calmolan can cause hallucinations (seeing, hearing or feeling things that are not there). If affected, do not drive or use machines.

Calmolan has been associated with sleepiness and episodes of suddenly falling asleep, particularly in patients with Parkinson's disease. If you experience these side effects, you must not drive or operate machinery. You should tell your doctor if this occurs.

3. How to take Calmolan

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The doctor will advise you on the right dosing.

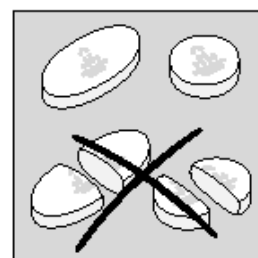
Take Calmolan prolonged-release tablets only once a day and each day at about the same time.

You can take Calmolan with or without food. Swallow the tablets whole with water.

Do not chew, divide or crush the prolonged-release tablets.

If you do, there is a danger you could overdose, because the medicine may be released into your body too quickly.

During the first week, the usual daily dose is 0.26 mg pramipexole. The dose will be increased every 5-7 days as directed by your doctor until your symptoms are controlled (maintenance dose).



Ascending dose schedule of Calmolan prolonged-release tablets		
Week	Daily dose (mg)	Number of tablets
1	0.26	One Calmolan 0.26 mg prolonged-release tablet.
2	0.52	One Calmolan 0.52 mg prolonged-release tablet, OR two Calmolan 0.26 mg prolonged-release tablets.
3	1.05	One Calmolan 1.05 mg prolonged-release tablet, OR two Calmolan 0.52 mg prolonged-release tablets,

		OR four Calmolan 0.26 mg prolonged-release tablets.
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The usual maintenance dose is 1.05 mg per day. However, your dose may have to be increased even further. If necessary, your doctor may increase your dose up to a maximum of 3.15 mg of pramipexole a day. A lower maintenance dose of one Calmolan 0.26 mg prolonged-release tablet a day is also possible.

Patients with kidney disease

If you have kidney disease, your doctor may advise you to take the usual starting dose of 0.26 mg prolonged-release tablets only every other day for the first week. After that, your doctor may increase the dosing frequency to one 0.26 mg prolonged-release tablet every day. If a further dose increase is necessary, your doctor may adjust it in steps of 0.26 mg pramipexole.

If you have serious kidney problems, your doctor may need to switch you to a different pramipexole medicine. If during treatment your kidney problems get worse, you should contact your doctor as soon as possible.

If you are switching from Calmolan (immediate release) tablets

Your doctor will base your dose of Calmolan prolonged-release tablets on the dose of Calmolan (immediate release) tablets you were taking.

Take your Calmolan (immediate release) tablets as normal the day before you switch. Then take your Calmolan prolonged-release tablets next morning and do not take any more Calmolan (immediate release) tablets.

If you take more Calmolan than you should

If you accidentally take too many tablets,

- contact your doctor or nearest hospital casualty department immediately for advice.
- You may experience vomiting, restlessness, or any of the side effects as described in chapter 4 "Possible side effects".

If you forget to take Calmolan

If you forget to take a dose of Calmolan, but remember within 12 hours of your usual time, take your tablet straightaway and then take your next tablet at the usual time.

If you forget for more than 12 hours, simply take the next single dose at the usual time. Do not take a double dose to make up for a forgotten tablet dose.

If you stop taking Calmolan

Do not stop taking Calmolan without first talking to your doctor. If you have to stop taking this medicine, your doctor will reduce the dose gradually. This reduces the risk of worsening symptoms.

If you suffer from Parkinson's disease you should not stop treatment with Calmolan abruptly. A sudden stop could cause you to develop a medical condition called neuroleptic malignant syndrome which may represent a major health risk. The symptoms include:

- akinesia (loss of muscle movement),
- rigid muscles,
- fever,
- unstable blood pressure,
- tachycardia (increased heart rate),
- confusion,
- depressed level of consciousness (e.g. coma).

If you stop or reduce Calmolan you may also develop a medical condition called dopamine agonist withdrawal syndrome. The symptoms include depression, apathy, anxiety, fatigue, sweating or pain. If you experience these symptoms, you should contact your physician.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Evaluation of these side effects is based on the following frequencies:

Very common	may affect more than 1 in 10 people
Common	may affect up to 1 in 10 people
Uncommon	may affect up to 1 in 100 people
Rare	may affect up to 1 in 1,000 people
Very rare	may affect up to 1 in 10,000 people
Not known	frequency cannot be estimated from the available data

You may experience the following side effects:

Very common

- Dyskinesia (e.g. abnormal, uncontrolled movements of the limbs)
- Sleepiness
- Dizziness
- Nausea (sickness)

Common

- Urge to behave in an unusual way
- Hallucinations (seeing, hearing or feeling things that are not there)
- Confusion
- Tiredness (fatigue)
- Sleeplessness (insomnia)
- Excess of fluid, usually in the legs (peripheral oedema)
- Headache
- Hypotension (low blood pressure)
- Abnormal dreams
- Constipation
- Visual impairment
- Vomiting (being sick)
- Weight loss including decreased appetite

Uncommon

- Paranoia (e.g. excessive fear for one's own well-being)
- Delusion
- Excessive daytime sleepiness and suddenly falling asleep
- Amnesia (memory disturbance)
- Hyperkinesia (increased movements and inability to keep still)
- Weight increase
- Allergic reactions (e.g. rash, itching, hypersensitivity)
- Fainting
- Cardiac failure (heart problems which can cause shortness of breath or ankle swelling)*
- Inappropriate antidiuretic hormone secretion*
- Restlessness
- Dyspnoea (difficulties to breathe)
- Hiccups
- Pneumonia (infection of the lungs)

- Inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others, which may include:
- Strong impulse to gamble excessively despite serious personal or family consequences.
- Altered or increased sexual interest and behaviour of significant concern to you or to others, for example, an increased sexual drive.
- Uncontrollable excessive shopping or spending
- Binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger)*
- Delirium (decreased awareness, confusion, loss of reality)

Rare

- Mania (agitation, feeling elated or over-excited)

Not known

- After stopping or reducing your Calmolan treatment: Depression, apathy, anxiety, fatigue, sweating or pain may occur (called dopamine agonist withdrawal syndrome or DAWS).

Tell your doctor if you experience any of these behaviors; he will discuss ways of managing or reducing the symptoms.

For the side effects marked with * a precise frequency estimation is not possible, since these side effects were not observed in clinical studies among 2,762 patients treated with pramipexole. The frequency category is probably not greater than “uncommon”.

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 national reporting system listed in Appendix V.*. By reporting side effects you can help provide more information on the safety of this medicine.

[*according to Appendix V – to be completed nationally]

5. How to store Calmolan

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 carton after {EXP}. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions.

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 Calmolan prolonged-release tablets contains

- The active substance is pramipexole.
Each tablet contains 0.26 mg, 0.52 mg, 1.05 mg, 1.57 mg, 2.1 mg, 2.62 mg, or 3.15 mg pramipexole as 0.375 mg, 0.75 mg, 1.5 mg, 2.25 mg, 3 mg, 3.75 mg, or 4.5 mg pramipexole dihydrochloride monohydrate, respectively.
- The other excipients are hypromellose, calcium hydrogen phosphate, magnesium stearate, silica, colloidal anhydrous.

What Calmolan prolonged-release tablets looks like and contents of the pack

Calmolan 0.26 mg prolonged-release tablets: The tablets of 9 mm are white or nearly white, round with flat surface and beveled edges, marked with 026 on one side

Calmolan 0.52 mg prolonged-release tablets: The tablets of 10 mm are white or nearly white, round, biconvex and marked with 052 on one side

Calmolan 1.05 mg prolonged-release tablets: The tablets of 10 mm are white or nearly white, round, biconvex, and marked with 105 on one side

Calmolan 1.57 mg prolonged-release tablets: The tablets of 10 mm are white or nearly white, round, biconvex and marked with 157 on one side

Calmolan 2.1 mg prolonged-release tablets: The tablets of 10 mm are white or nearly white, round, biconvex and marked with 210 on one side

Calmolan 2.62 mg prolonged-release tablets: The tablets of 10 mm are white or nearly white, round, biconvex and marked with 262 on one side

Calmolan 3.15 mg prolonged-release tablets: The tablets of 11 mm are white or nearly white, round with flat surface and beveled edges, marked with 315 on one side

Blister Al/OPA-Al-PVC: 10, 30 and 100 prolonged-release tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Pramipexol G.L. 0,26 mg Retardtabletten Pramipexol G.L. 0,52 mg Retardtabletten Pramipexol G.L. 1,05 mg Retardtabletten Pramipexol G.L. 1,57 mg Retardtabletten Pramipexol G.L. 2,1 mg Retardtabletten Pramipexol G.L. 2,62 mg Retardtabletten Pramipexol G.L. 3,15 mg Retardtabletten
Czech Republic	Calmolan 0,26 mg Calmolan 0,52 mg Calmolan 2,1 mg
Hungary	Calmolan 0,26 mg retard tabletta Calmolan 0,52 mg retard tabletta Calmolan 1,05 mg retard tabletta Calmolan 2,1 mg retard tabletta Calmolan 3,15 mg retard tabletta
Romania	Calmolan 0,26 mg comprimate cu eliberare prelungita Calmolan 0,52 mg comprimate cu eliberare prelungita Calmolan 2,1 mg comprimate cu eliberare prelungita
Sweden	Calmolan

This leaflet was last revised in 23 October 2024.