

PACKAGE LEAFLET: Information for the patient

PARKINSAN

Tablets – 5 mg

(Trihexyphenidyl hydrochloride)

Read all of this leaflet carefully before you start taking this medicine.

- 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 on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Parkinsan is and what it is used for
2. Before you take Parkinsan
3. How to take Parkinsan
4. Possible side effects
5. How to store Parkinsan
6. Further information

1. WHAT PARKINSAN IS AND WHAT IT IS USED FOR

Parkinsan contains the active substance trihexyphenidyl hydrochloride.

It is an antimuscarinic agent with similar effects as atropine.

It exerts direct inhibitory effect on the parasimpatique nervous system by inhibiting the effects of acetylcholine.

Parkinsan has also an antispasmodic effect on the smooth muscles.

Parkinsan 5 mg tablets are indicated:

- as supportive treatment for all forms of parkinsonism (postencephalytic, arteriosclerotic and idiopathic);
- as adjuvant therapy when treating the above-mentioned forms of parkinsonism with levodopa. It helps in reducing muscle rigidity and increased salivation that accompanies parkinsonism;
- as adjuvant therapy when using levodopa to control extrapyramidal disorders due to central nervous system drugs.

2. BEFORE YOU TAKE PARKINSAN**Do not take Parkinsan if:**

- you are hypersensitive to trihexyphenidyl or to any of the excipients of this medication, mentioned at the end of this leaflet;
- you have urinary retention;
- you suffer from closed-angle glaucoma;
- you have gastrointestinal obstruction;
- you suffer from Myasthenia gravis.

Take special care with Parkinsan:

Ask your doctor before you take Parkinsan if:

- you suffer from arrhythmia (primarily tachycardia), hypertension, hypotension;
- you have prostatic hypertrophy;
- you have renal or hepatic impaired function;
- you suffer from megacolon.

Special care should be done during hot weather because a reduction of the secretions and fatal hyperthermia may occur.

Trihexyphenidyl may become subject to abuse if used in high doses (because of its hallucinogenic and euphoric properties which are usual for all anticholinergic drugs).

Generally anticholinergics should be used with caution in patients treated with tricyclic antidepressants or monoaminooxidase inhibitors (MAOI). In patients taking antidepressants, the dose of trihexyphenidyl must be lowered in the beginning and the patients should stay under control.

The lowest dose of the effective interval is recommended for elderly patients and patients suffering from arteriosclerosis because they are more susceptible to the side effects of antimuscarinic drugs.

Taking other medicines

Concomitant treatment with other drugs may affect or be affected by Parkinsan. Please consult your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription.

Do not forget to inform your doctor that you are taking Parkinsan if you must take any other drug during treatment, especially the following:

- *other antimuscarinic drugs*: the simultaneous use of two or three of these medicines can increase side effects, such as: dry mouth, urinary retention and constipation. Their simultaneous use in the elderly can lead to confusion;
- *antiarrhythmics*: increase of antimuscarinic effects with disopiramide;
- *antihistamines*: increase of antimuscarinic side effects;
- *antimycotics*: decreased absorption of ketoconazole;
- *haloperidol*: symptoms of schizophrenia may deteriorate when trihexyphenidyl is used simultaneously with haloperidol because levels of haloperidol can decrease and tardive dyskinesia may appear;
- *phenothiazines*: their effects may be decreased by trihexyphenidyl;
- *tricyclic antidepressants* or *monoamine oxidase inhibitors (MAOI)*;
- *amantadine*: the antimuscarinic undesirable effects may be increased;
- *nitrates*: reduction of the effect of sublingual nitrates (sublingual dissolution is delayed due to drying of the mouth).

Pregnancy

Parkinsan should not be used during pregnancy unless clearly necessary!

Inform your doctor or pharmacist if you are pregnant or are planning to become pregnant.

Your doctor should assess the risk to which is exposed the fetus and the mother benefit from treatment with Parkinsan.

Breastfeeding

Parkinsan should not be used during breastfeeding.

Inform your doctor or pharmacist if you feed your baby with breastmilk.

Driving and using machines

Parkinsan can cause blurring of vision or decreased alertness, so special care is required during driving or using machinery.

Important information about some of the excipients of Parkinsan

This tablet 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.

3. HOW TO TAKE PARKINSAN

Always take Parkinsan as your doctor has told you. If you are not sure, contact your doctor or pharmacist. If you feel that the effects of Parkinsan are too strong or too weak, contact your doctor or pharmacist. The tablets should be taken with a glass of water.

The dosage for the tablet is as described below:

In Parkinson disease 3-4 divided doses daily, before meals or during them.

The usual initial dose of 1 mg/day is increased gradually in steps of 2 mg every 3-5 days up to 6-10 mg/daily according to the patient response. In advanced cases, 12-15 mg/daily or more may be needed. Post-encephalytic patients need and tolerate higher doses.

In extrapyramidal disorders caused from drugs the usual doses are between 5-15 mg/daily, although in some cases 1 mg / day may be sufficient.

Since the elderly and arteriosclerotic patients are affected more by the side effects of antimuscarinic drugs, the lowest dose of the effective interval is recommended.

Treatment of parkinsonism with antimuscarinic drugs should not be interrupted immediately, and if it should switch from one drug to another, the dose of one of them should decrease gradually while the dose of the other drug is increased.

This drug can be given in combination with other drugs to facilitate parkinsonism, but the dose of each drug should be reduced.

If you take more Parkinsan than you should

If you take more Parkinsan than you should, or if the children take it by accident, please contact your doctor, the hospital, or call the emergency to get an opinion on the risk and advice on the actions to be taken.

If you forget to take Parkinsan

If you forget a dose (or more doses), take the following dose when it is time to take it usually.

Do not take a double dose (or higher) to make up the forgotten dose (doses).

If you stop taking Parkinsan

Immediate termination should be avoided. Dose reduction should be realized gradually.

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

4. POSSIBLE SIDE EFFECTS

Like all other medicines, Parkinsan can cause side effects, although not everyone manifests them. Talk to your doctor for the following side effects that you may experience:

- in the cardiovascular system (tachycardia, palpitations, hypotension);
- in the central nervous system (dizziness, nervousness, psychiatric manifestations, such as: delusions or hallucinations, mental confusion, agitation, behavior disorders);
- in the gastrointestinal tract (dryness of mouth, nausea, vomiting, constipation, suppurative parotitis, paralytic ileus, megacolon);
- eczanthema;
- blurred vision;
- urinary retention, impotence;
- chills, flushing and decreased sweating.

If any of the side effects gets worse or if you experience side effects that are not mentioned in this leaflet, please talk to your doctor or pharmacist.

5. HOW TO STORE PARKINSAN

Keep out of the reach and sight of children!

Do not use Parkinsan after the expiry date which is stated on the packaging.

Do not store above 25 °C!

Keep in the original packaging to protect it from light!

6. FURTHER INFORMATION

What Parkinsan contains

The active substance is trihexyphenidyl hydrochloride.

Each tablet contains 5 mg trihexyphenidyl hydrochloride.

The excipients are lactose, microcrystalline cellulose, talc, magnesium stearate.

Content of the pack

Box with 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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