

PACKAGE LEAFLET: INFORMATION FOR THE USER

Permixon® 160 mg

hard capsules

Lipidosterolic extract of *Serenoa repens*

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

1. What PERMIXON is and what it is used for
Permixon belongs to the group of medicines used in benign prostatic hypertrophy and acts at the prostatic level improving the symptoms associated with benign prostatic hypertrophy. Permixon is used in male adult in the treatment of moderate urination disorders associated with benign prostatic hypertrophy.

2. What you need to know before you take PERMIXON

Do not take PERMIXON

if you are allergic to the active substance lipidosterolic extract of *Serenoa repens* or to any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking PERMIXON.

Drug administration on empty stomach may cause nausea and should therefore be administered with meals.

Permixon cannot substitute prostatectomy and, during treatment, you must be under continuous medical surveillance.

Interaction of PERMIXON with other medicines

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

No interferences with other medicines frequently used to treat this disease (urinary antibiotics, antiseptics and antiinflammatory agents) have been observed. To avoid possible interactions between several medicines, you must tell your doctor or pharmacist all other treatments you are following.

PERMIXON with food and drinks

It is recommended to take PERMIXON during meals and with a glass of water without chewing.

Pregnancy and breast-feeding and fertility

This medicinal product is not indicated in women.

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

Driving and using machines

Effects on driving and using machines were not observed.

3. How to take PERMIXON

Always take PERMIXON exactly as your doctor has told you. If you have any further questions, ask your doctor or pharmacist.

The recommended dose is one capsule, twice per day, at meals, with the help of a little bit of water.

Use in children and adolescents

This medicinal product is not indicated in children and adolescents.

If you take more PERMIXON than you should

The appearance of symptoms is transient gastrointestinal disorders (abdominal pain).

In case of overdose or accidental ingestion, consult your doctor or pharmacist.

If you forget to take PERMIXON

Do not take a double dose to make up a forgotten dose.

Continue treatment without changing the dosage.

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

4. Possible side effects

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

The side effects that can occur are:

Commonly (affect 1 to 10 in 100 people)

- Headache.
- Abdominal pain.

Uncommonly (affect 1 to 10 in 1000 people)

- Nausea.
- Increase of Gamma glutamyltransferase, moderate increase of transaminases (liver enzymes).
- Reddening of the skin (rash).
- Gynecomastia (enlargement of mammary glands in men). Reversible upon discontinuation of treatment.

With an unknown frequency (frequency cannot be estimated from the available data)

- CEdema.

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. By reporting side

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

5. How to store PERMIXON

Do not store above 25°C.

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. The expiry date refers to the last day of that month.

Do not throw away 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 package and other information

Composition of PERMIXON

- The active substance is lipidosterolic of *Serenoa repens**, 160 mg.

* Oil extract originated from fruits of *Serenoa repens* (Bartram) Small.

Drug extract ratio 7-11:1

Extraction solvent : hexanic solvent

- The other components are macrogol 10 000, gelatin, yellow iron oxide E 172, indigotin E 132, titanium dioxide E 171.

What Permixon looks like and contents of the package

Each box of PERMIXON contains 30 or 60 hard capsules in PVC/Aluminium blister.

Not all pack sizes may be registered.

The hard capsules are pale green and contain a yellow-green paste.

Marketing Authorisation Holder

Pierre Fabre Medicament
45, Place Abel Gance
92100 Boulogne - France

Manufacturer

Pierre Fabre Medicament Production
45, Place Abel Gance
92100 Boulogne - France

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