Package leaflet: Information for the user

Caristenol 2 mg prolonged-release capsules
Caristenol 4 mg prolonged-release capsules
tolterodine tartrate

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 Caristenol is and what it is used for

The active substance in Caristenol is tolterodine.

Tolterodine belongs to a class of medicinal products called antimuscarinics. Caristenol is used for the treatment of the symptoms of overactive bladder syndrome.
If you have overactive bladder syndrome, you may find that:
- you are unable to control urination,
- you need to rush to the toilet with no advance warning and/or go to the toilet frequently.

2. What you need to know before you take Caristenol

Do not take Caristenol if you:

- are allergic (hypersensitive) to tolterodine or any of the other ingredients of this medicine (listed in section 6)
- are unable to pass urine from the bladder (urinary retention)
- have an uncontrolled narrow-angle glaucoma (high pressure in the eyes with loss of eyesight that is not being adequately treated)
- suffer from myasthenia gravis (excessive weakness of the muscles)
- suffer from severe ulcerative colitis (ulceration and inflammation of the colon)
- suffer from a toxic megacolon (acute dilatation of the colon).

Warnings and precautions

Tell your doctor before you take these capsules if you:

- have difficulties in passing urine and/or a poor stream of urine
- have a gastro-intestinal disease that affects the passage and/or digestion of food

- suffer from kidney problems (renal insufficiency)
- have a liver condition
- suffer from neuronal disorders that affect your blood pressure, bowel or sexual function (any neuropathy of the autonomic nervous system)
- have a hiatal hernia (herniation of an abdominal organ)
- ever experience decreased bowel movements or suffer from severe constipation (decreased gastro-intestinal motility)
- have a heart condition such as:
    - an abnormal heart tracing (ECG);
    - a slow heart rate (bradycardia);
    - relevant pre-existing cardiac diseases such as:
        - cardiomyopathy (weak heart muscle)
        - myocardial ischaemia (reduced blood flow to the heart)
        - arrhythmia (irregular heartbeat)
        - and heart failure
- have abnormally low levels of potassium (hypokalaemia), calcium (hypocalcaemia) or magnesium (hypomagnesaemia) in your blood.

Talk to your doctor or pharmacist before starting your treatment with Caristenol if you think any of these might apply to you.

Other medicines and Caristenol

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Tolterodine, the active substance of Caristenol, may interact with other medicinal products.

It is not recommended to use tolterodine in combination with:
- some antibiotics (containing e.g. erythromycin, clarithromycin)
- medicinal products used for the treatment of fungal infections (containing e.g. ketoconazole, itraconazole)
- medicinal products used for the treatment of HIV.

Caristenol should be used with caution when taken in combination with:
- medicines that affect the passage of food (containing e.g. metoclopramide and cisapride)
- medicines for the treatment of irregular heartbeat (containing e.g. amiodarone, sotalol, quinidine, procainamide)
- other medicines with a similar mode of action to Caristenol (antimuscarinic properties) or medicines with an opposite mode of action to Caristenol (cholinergic properties). Ask your doctor if you are unsure.

Caristenol with food and drink
Caristenol can be taken before, after or during a meal.

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.

Pregnancy
You should not use Caristenol when you are pregnant. Tell your doctor immediately if you are pregnant, think you are pregnant or are planning to become pregnant.

Breast-feeding
It is not known if tolterodine, the active substance of Caristenol, is excreted in the mother’s breast

milk. Breast-feeding is not recommended during administration of Caristenol.

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

Driving and using machines
Caristenol may make you feel dizzy, tired or affect your sight; your ability to drive or operate machinery may be affected.

3. How to take Caristenol

Dosage
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one 4 mg prolonged-release capsule daily, except for patients who have a kidney or a liver condition or troublesome side effects, in which case your doctor may reduce your dose to 2 mg Caristenol daily.

Caristenol is not recommended for children.

The prolonged-release capsules are for oral use and should be swallowed whole. Do not chew the capsules.

Duration of treatment
Your doctor will tell you how long your treatment with Caristenol will last. Do not stop treatment early because you do not see an immediate effect. Your bladder will need some time to adapt. Finish the course of prolonged-release capsules prescribed by your doctor. If you have not noticed any effect by then, talk to your doctor.

The benefit of the treatment should be re-evaluated after 2 or 3 months.

Always consult your doctor if you are thinking of stopping the treatment.

If you take more Caristenol than you should
If you or somebody else takes too many prolonged-release capsules, contact your doctor or pharmacist immediately.

If you forget to take Caristenol
If you forget to take a dose at the usual time, take it as soon as you remember unless it is almost time for your next dose. In that case, omit the forgotten dose and follow the normal dose schedule.
Do not take a double dose to make up for a forgotten dose.

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.

You should see your doctor immediately or go to the casualty department if you experience symptoms of angioedema, such as:
- swollen face, tongue or pharynx
- difficulty to swallow
- hives and difficulty in breathing

You should also seek medical attention if you experience a hypersensitivity reaction (for example itching, rash, hives, difficulty breathing). This occurs uncommonly (may affect up to 1 in 100 people).

Tell your doctor immediately or go to the casualty department if you notice any of the following:
- chest pain, difficulty breathing or getting tired easily (even at rest), difficulty breathing at night, swelling of the legs.

These may be symptoms of heart failure. This occurs uncommonly (may affect up to 1 in 100 people).

The following side effects have been observed during treatment with Caristenol with the following frequencies.

Very common side effects (may affect more than 1 in 10 people) are:
- Dry mouth

Common side effects (may affect up to 1 in 10 people) are:
- Sinusitis
- Dizziness, sleepiness, headache
- Dry eyes, blurred vision
- Difficulty with digestion (dyspepsia), constipation, abdominal pain, excessive amounts of air or gases in the stomach or the intestine
- Painful or difficult urination
- Tiredness
- Extra fluid in the body causing swelling (e.g. in the ankles)
- Diarrhoea

Uncommon side effects (may affect up to 1 in 100 people) are:
- Allergic reactions
- Nervousness
- Sensation of pins and needles in the fingers and toes
- Vertigo
- Palpitations, heart failure, irregular heartbeat
- Inability to empty the bladder
- Chest pain
- Memory impairment

Additional reactions reported include severe allergic reactions, confusion, hallucinations, increased heart rate, flushed skin, heart burn, vomiting, angioedema, dry skin, and disorientation. There have also been reports of worsening symptoms of dementia in patients being treated for dementia.

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
HPRA Pharmacovigilance
Website: www.hpra.ie

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

5. How to store Caristenol

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and on the blister after "EXP". The expiry date refers to the last day of that month.

Do not use this medicine if you notice the pack that is damaged or shows signs of tampering.

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 to protect the environment.

6. Contents of the pack and other information

What Caristenol contains

The active substance is tolterodine.

For 2 mg: Each prolonged-release capsule contains tolterodine tartrate 2 mg corresponding to 1.37mg tolterodine.
For 4 mg: Each prolonged-release capsule contains tolterodine tartrate 4 mg corresponding to 2.74mg tolterodine.

The other ingredients are:
Capsule contents: Microcrystalline cellulose spheres, hypromellose, talc, ethylcellulose, medium chain triglycerides and oleic acid.

Capsule shell: Gelatin, indigo carmine (E132), titanium dioxide (E171) and yellow iron oxide (E172) (for 2mg only).

Printing ink [Shellac, titanium dioxide, propylene glycol, potassium hydroxide and ammonium hydroxide].

What Caristenol looks like and contents of the pack

Caristenol 2 mg are dark green/dark green size '4', approximately 14 mm in length, hard gelatin capsule with imprinting bar lines on cap and body.
Caristenol 4 mg are dark blue /dark blue size '3', approximately 16 mm in length, hard gelatin capsule with imprinting bar lines on cap and body.

Caristenol 2mg/4 mg are available in Aluminium -PVC/PVdC blister pack.

Pack sizes: 7, 10, 14, 20, 28, 30, 49, 50, 56, 60, 80, 84, 90, 98,100, 112, 160, 200, 280 or 320 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Accord Healthcare Ireland Ltd,
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Manufacturer
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This medicinal product is authorised in the Member States of the EEA under the following names:

Member States	Invented Names
Austria	Tolterodine Accord 2/4 mg Hartkapsel, retardiert
Bulgaria	Tolterodine Акорд 2/4 мг Капсула с удълженоосвобождаване, твърда
Estonia	Tolterodine Accord
Finland	Tolterodine Accord 2mg/4mg depotkapseli, kova
Ireland	Caristenol 2/4 mg prolonged-release capsules
Lithuania	Tolterodine Accord 2/4 mg pailginto atpalaidavimo kietosios kapsulės
Netherland	Tolterodine Accord 2/4 mg capsules met verlengde afgifte, hard
Norway	Caristenol
Poland	Caristenol
Sweden	Tolterodine Accord 2/4 mg Depotkapsel, hård
United Kingdom	Caristenol 2/4 mg prolonged-release capsules

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