Consilient Health

PACKAGE LEAFLET: INFORMATION FOR THE USER

Tamsulosin hydrochloride Consilient Health 400 microgram prolonged-release hard capsules

tamsulosin hydrochloride

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.

In this leaflet:

1. What Tamsulosin capsules are and what they are used for
2. What you need to know before you take Tamsulosin capsules
3. How to take Tamsulosin capsules
4. Possible side effects
5. How to store Tamsulosin capsules
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1. WHAT TAMSULOSIN CAPSULES ARE AND WHAT THEY ARE USED FOR

The name of this medicine is Tamsulosin hydrochloride Consilient Health 400 microgram prolonged-release hard capsules (referred to as Tamsulosin capsules throughout this leaflet).

Tamsulosin is an alpha1A-adrenoreceptor blocker. It relaxes the muscles in the prostate and urinary tract.

Tamsulosin is prescribed to alleviate urinary symptoms caused by an enlarged prostrate (benign prostatic hyperplasia). By relaxing the muscle it enables a more easily pass of urine and helps urination.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TAMSULOSIN CAPSULES

Do not take Tamsulosin capsules
- if you are **allergic** to tamsulosin or any of the other ingredients of this medicine (listed in section 6) (symptoms may include: **swelling of your face and throat** (angio-oedema)).
- if you have a history of a fall in blood pressure on standing up, which causes **dizziness, light-headedness or fainting**.
- if you have **severe liver problems**

Warnings and precautions
Talk to your doctor or pharmacist before taking Tamsulosin capsules
- if you experience **dizziness or light-headedness**, especially after standing up. Tamsulosin may lower your blood pressure, causing these symptoms. You should sit or lie down until the symptoms have gone.
- if you suffer from **severe kidney problems**. The normal dose of tamsulosin may not have the expected effect when your kidneys are not functioning normally.
- if you are undergoing **eye surgery** because of cloudiness of the lens (cataract). An eye condition called Intraoperative Floppy Iris Syndrome may occur (see section 4, Possible side effects), please inform your eye specialist that you are using or have previously used tamsulosin hydrochloride. The specialist can then take appropriate precautions with respect to medication and surgical techniques to be used. Ask your doctor whether or not you should postpone or temporarily stop taking this medicine when undergoing eye surgery because of a cloudy lens (cataract) or increased pressure of the eye (glaucoma).

Before starting therapy with tamsulosin, your doctor should examine you to confirm your symptoms are truly caused by an enlarged prostate.

Children and adolescents
Do not give this medicine to children or adolescent under 18 years because it does not work in this population.

Other medicines and Tamsulosin capsules
Other medicines may be affected by tamsulosin. They, in turn, may affect how well tamsulosin works. Tamsulosin can interact with:
- **diclofenac**, a pain killer and anti-inflammatory medicine. This medicine can speed up the removal of tamsulosin from your body, thereby shortening the time tamsulosin is effective.
- **warfarin**, a medicine to prevent blood clotting. This medicine can speed up the removal of tamsulosin from your body, thereby shortening the time tamsulosin is effective.
- **another α_1-adrenoreceptor blocker**. The combination may lower your blood pressure, causing dizziness or light-headedness.
- **ketoconazole**, a medicine to treat fungal skin infections. This medicine may increase the effect of tamsulosin.

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

Tamsulosin capsules with food and drink
You should take tamsulosin with a glass of water after breakfast or after your first meal of the day.

Pregnancy, breast-feeding and fertility
Tamsulosin is not indicated for use in women.

In men, abnormal ejaculation has been reported (ejaculation disorder). This means that the semen does not leave the body via the urethra, but instead goes into the bladder (retrograde ejaculation) or the ejaculation volume is reduced or absent (ejaculation failure). This phenomenon is harmless.

Driving and using machines
There is no information on the effects of tamsulosin on the ability to drive and use machines. You should take into account that tamsulosin may cause dizziness and light-headedness. Only drive or use machines if you feel alright.

Tamsulosin capsules contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. HOW TO TAKE TAMSULOSIN CAPSULES

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 capsule per day taken **after breakfast** or after your first meal of the day.

Swallow the capsule **whole** with a glass of water, while standing or sitting (not while lying down). It is important that you **do not break or crush the capsule** as this may influence how well tamsulosin

works.

If you suffer from mild to moderate kidney or liver disease, you can take the usual dose of tamsulosin.

If you take more Tamsulosin capsules than you should
Your blood pressure may suddenly drop if you take more tamsulosin than you should. You may experience dizziness, weakness and fainting, vomiting and diarrhoea. Lie down to minimise the effects of low blood pressure and then contact your doctor. Your doctor may give you medicines to restore you blood pressure and fluid level, and may monitor your body function. When necessary your doctor may empty your stomach and give you a laxative to remove any tamsulosin not yet taken up in the blood from your body.

If you forget to take Tamsulosin capsules
Do not take a double dose to make up for a forgotten dose. Just take the next dose at the usual time.

If you stop taking Tamsulosin capsules
When treatment with tamsulosin is stopped prematurely, your original complaints may return. Therefore use tamsulosin as long as your doctor prescribes, even if your complaints have disappeared already. Always consult your doctor, if you consider stopping this therapy.

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.

Serious reactions are very rare. **Contact your doctor immediately** if you experience **a serious allergic reaction which causes swelling of the face or throat** (angio-oedema). You should not be restarted on tamsulosin (see Section 2, Do not take tamsulosin).

Common side effects
(may affect up to 1 in 10 people)
- Dizziness, particularly when going to sit or stand up
- Abnormal ejaculation (ejaculation disorder). This means that semen does not leave the body via the urethra, but instead goes into the bladder (retrograde ejaculation) or the ejaculation volume is reduced or absent (ejaculation failure). This phenomenon is harmless.

Uncommon side effects
(may affect up to 1 in 100 people)
- Headache
- Feeling your heart beat (palpitations)
- a Fall in blood pressure on standing up, which causes dizziness, light-headedness or fainting (orthostatic hypotension)
- Swelling and irritation inside the nose (rhinitis)
- Constipation
- Diarrhoea
- Feeling sick (nausea)
- Vomiting
- Rash
- Hives (urticaria)
- Feeling of weakness (asthenia)
- Itching

Rare side effects
(may affect up to 1 in 1,000 people)
- Fainting (syncope)

Very rare side effects
(may affect up to 1 in 10,000 people)
- Painful erection (priapism)
- Serious illness with blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome)

Not known side effects (frequency cannot be estimated from the available data)
- Blurred vision
- Visual impairment
- Nose bleeds (epistaxis)
- Dry mouth
- Serious skin rashes (erythema multiform, dermatitis exfoliative)
- Abnormal irregular heart rhythm (atrial fibrillation, arrhythmia, tachycardia), difficult breathing (dyspnoea)

During eye surgery because of cloudiness of the lens (cataract) or increased pressure in the eye (glaucoma) a condition called Floppy Iris Syndrome (IFIS) may occur: the pupil may dilate poorly and the iris (the coloured circular part of the eye) may become floppy during surgery. For more information see section 2, Warnings and precautions.

Reporting of side effects
If you get other 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 Yellow Card Scheme (website: www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TAMSULOSIN CAPSULES

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 and the blister or container after 'EXP'. The expiry date refers to the last day of that month.

Store the blisters in the original package.

Keep the container tightly closed.

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 Tamsulosin capsules contain
- The active substance is tamsulosin hydrochloride 0.4 mg.
- The other ingredients are:

Capsule: Microcrystalline cellulose, Methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 per cent, Polysorbate 80, Sodium laurilsulfate, Triethyl citrate, Talc
Capsule body: Gelatine, Indigo carmine (E 132), Titanium dioxide (E 171), Yellow iron oxide (E 172), Red iron oxide (E 172), Black iron oxide (E 172)

What Tamsulosin capsules look like and contents of the pack
Orange/olive-green prolonged-release hard capsules (19.3 x 6.4 mm). The capsules contain white to off-white pellets.

They are supplied in blister packs or containers with 10, 14, 20, 28, 30, 50, 56, 60, 90, 100 or 200 prolonged-release hard capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
Consilient Health Limited,
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