Package Leaflet: Information for the patient

Tamsu 400 micrograms Modified-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.

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

1. What Tamsu is and what it is used for

Tamsu modified-release capsules are used for the treatment of urination symptoms caused by benign prostatic hyperplasia (BPH - enlarged prostate).
These symptoms may include difficulty urinating (poor stream), dribbling, urgency and having to urinate frequently at night as well as during the day.
The active ingredient in the capsules is a so-called alpha $_{1A}$-blocker that reduces muscle contraction in the prostate and urethra. This facilitates the flow of urine through the urethra and aids urination.

2. What you need to know before you take Tamsu

Do not take Tamsu
- If you are allergic to tamsulosin hydrochloride or any of the other ingredients of this medicine (listed in section 6). Allergy to tamsulosin hydrochloride can express itself as sudden swelling of hands or feet, difficulties in breathing and/or itch and rash (angio-oedema).
- If you have experienced dizziness or have fainted from lowered blood pressure (e.g. when suddenly sitting or standing up).
- If you have been found to suffer from severe liver problems.

Warnings and precautions
Talk to your doctor or pharmacist before taking Tamsu
- If you have been found to suffer from severe kidney problems.
- If you experience dizziness or fainting during the use of Tamsu. Please sit or lie down straight away until the symptoms disappear.
- If you experience sudden swelling of hands or feet, difficulties in breathing and/or itch and rash, caused by an allergic reaction (angio-oedema) during the use of Tamsu.
- If you are undergoing or have been scheduled for eye surgery because of cloudiness of the lens (cataract) or increased pressure in the eye (glaucoma). An eye condition called Intraoperative Floppy Iris Syndrome may occur (see section 4, Possible side effects), please inform your eye specialist that you have previously used, are using, or are planning to use Tamsu. 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 or increased pressure in the eye.

Please consult your doctor, even if these statements were applicable to you at any time in the past.

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

Other medicines and Tamsu
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor or pharmacist if you are taking:
- Diclofenac (an anti-inflammatory painkiller) and warfarin (used to prevent blood clotting) may have an influence on how fast Tamsu is removed from the body.
- Medicines that lower your blood pressure such as verapamil and diltiazem.
- Medicines to treat HIV such as ritonavir or indinavir.
- Medicines to treat a fungal infection such as ketaconazole or itraconazole
- Other α_{1A}drenoreceptor blocker such as doxazosin, indoramin, prazosin or alfuzosin. The combination may lower your blood pressure, causing dizziness or light-headedness.
- Erythromycin, an antibiotic used to treat infections.

Tamsu with food and drink
Tamsu should be taken after the first meal of the day. Taking Tamsu on an empty stomach may increase the number of side effects or increase the severity of a side effect.

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

Driving and using machines
Up until now, there is no evidence that Tamsu affects the ability to drive or use machines.
Patients should nevertheless be aware that dizziness may occur.

3. How to take Tamsu

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

The recommended dose is one capsule a day after the first meal of the day.

Take the capsule while standing or sitting upright (not lying down) and swallow the capsule whole with a glass of water.
Do not chew the capsule.

Your physician has prescribed a suitable dose for you and your illness, and has specified the duration of the treatment.
You should not change the dose without speaking to your doctor first. If you have the impression that the effect of Tamsu is too strong or too weak, talk to your doctor or pharmacist.

No dose adjustment is needed when you have problems with your kidneys, or mild to moderate impairment of your liver function. Do not take this medicine if you have severe liver problems (See Section 2).

If you take more Tamsu than you should
If you may have taken more Tamsu than you should, talk to your doctor or pharmacist immediately.

If you forget to take Tamsu
If you have forgotten to take Tamsu after the first meal of the day, it can be taken later the same day after food. If you have missed a day, just continue to take your daily capsule as prescribed.
Do not take a double dose to make up for a forgotten dose.

If you stop taking Tamsu
Do not stop taking Tamsu unless your doctor tells you so because stopping may cause your symptoms to reappear or worsen.

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

4. Possible side effects
Like all medicines, this medicine can have side effects, although not everybody gets them.

Serious side effects are rare or very rare. Stop taking this medicine and see a doctor straight away if you experience any of the following symptoms - you may need medical treatment:
- Allergic reaction - (may affect up to 1 in 1,000 people). The signs may include finding it difficult to breathe, having an itchy rash, having a swollen face, throat, or tongue
- Long-lasting and painful erection (usually not during sexual activity) – (may affect up to 1 in 10,000 people)
- A severe skin reaction with symptoms that could include skin blistering and exfoliation (known as Stevens-Johnson syndrome, erythema multiforme, or exfoliative dermatitis). (Not known, frequency cannot be estimated from the available data).

The following side effects have also been reported:

Especially when you sit or stand up
- Feeling dizzy (common - may affect up to 1 in 10 people)
- Feeling weak (uncommon - may affect up to 1 in 100 people)

If this happens, sit or lie down straight away until you feel better.

Common (may affect up to 1 in 10 people)
- Abnormal ejaculation (ejaculation disorders). 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 (may affect up to 1 in 100 people)
- Headache
- Fast heart beat (palpitations)
- Runny or blocked nose
- Feeling sick or being sick
- Diarrhoea or constipation
- Itching or lumpy rash (urticaria)

Rare (may affect up to 1 in 1,000 people)
- Feeling faint

Very rare (may affect up to 1 in 10,000 people)
- During an operation on the eye for cloudiness of the lens (cataract) or high pressure in the eye (glaucoma), the pupil (the black circle in the middle of your eye) may not increase in size as needed. Also, the iris (the coloured part of the eye) may become floppy during surgery.

Not Known (frequency cannot be estimated from the available data)
- Blurred vision or impaired vision
- Nose bleeds
- Dry mouth
- Irregular heart beat
- Difficulties breathing

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tamsu
Keep this medicine out of the sight and reach of children.

Store in the original package.
Keep the container tightly closed.

Do not use this medicine after the expiry date which is stated on the label of the container, the blisters and on the outer package after EXP. The expiry date refers to the last day of the month.

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 Tamsu contains
One modified-release capsule contains 0.4 mg of tamsulosin hydrochloride as the active ingredient.
The other ingredients are: microcrystalline cellulose, methacrylic acid-ethyl acrylate copolymer (1:1), polysorbate 80, sodium laurilsulfate, triethyl citrate and talc.
The capsule body ingredients are gelatine, indigo carmine (E 132), titanium dioxide (E 171), yellow iron oxide (E 172), red iron oxide (E 172) and black iron oxide (E 172).

What Tamsu looks like and contents of the pack
The Tamsu modified-release capsules are orange/olive-green in colour.

They are available in blister packaging or in containers of 10, 14, 20, 28, 30, 50, 56, 60, 90, 100 or 200 modified-release capsules
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers
Salutas Pharma GmbH, Dieselstr. 5, D-70839 Gerlingen, Germany.
Synthon Hispania S.L., Castello 1, Poligono Las Salinas, E-08833 Sant Boi de Llobregat, Spain.
Synthon B.V., Microweg 22, NL-6545 CM Nijmegen, The Netherlands.
Rowa Pharmaceuticals Ltd., Newtown, Bantry, Co. Cork, Ireland.
Lek S.A., Ul. Domaniewska 50C, PL-02-672 ,Warszawa, Poland.

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

Germany	Tamsulosin HEXAL 0,4 mg retard Hartkapseln mit veränderter Wirkstofffreisetzung
Austria	Tamsulosin Hexal retard 0,4 mg – Kapseln
Belgium	Tamsulosine Bexal 0.4 mg capsules met verlengde afgifte
Czech Republic	Tamsulosin HCl Sandoz 0,4 mg
Spain	Tamsulosina Bexal 0.4 mg cápsulas duras de liberacion prolongada EFG
Hungary	Tamsulosin Sandoz 0,4 mg retard kapszula
Ireland	Tamsu 400 micrograms Modified-Release Hard Capsules
Italy	TAMSULOSINA Hexal 0,4 mg capsule rigide a rilascio modificato, 20 capsule in blister
Luxemburg	Tamsulosin HEXAL 0,4 mg retard Hartkapseln mit veränderter Wirkstofffreisetzung
Poland	TamsuLEK
Slovenia	Tamsulozin Lek 0,4 mg trde kapsule s podaljšanim sproščanjem

This leaflet is last revised in: 10/2015.

I.M. L/96a 10-15
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