ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Xatral 2.5 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains

Alfuzosin hydrochloride ..... 2.5 mg

Excipient with known effect: lactose monohydrate.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablets.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Treatment of the functional symptoms of benign prostatic hypertrophy.

4.2. Posology and method of administration

Posology

Oral use.

Adults

The recommended dosage is one Xatral 2.5 mg tablet three times daily.

Elderly patients or patients treated for hypertension

As a systematic precaution, it is recommended that treatment be started with one Xatral 2.5 mg tablet morning and evening and that the dosage then be increased on the basis of the patient's individual response, without exceeding the maximum dosage of four Xatral 2.5 mg tablets daily.

Patients with liver failure

It is recommended that treatment be started with one Xatral 2.5 mg tablet per day and that the dosage then be increased on the basis of the patient's individual response, without exceeding the maximum dosage of one Xatral 2.5 mg tablet twice daily.

Paediatric population

Efficacy of alfuzosin has not been demonstrated in children aged 2 to 16 years (see section 5.1). Therefore, alfuzosin is not indicated for use in paediatric population.

4.3. Contraindications

This medicinal product must not be administered in the following situations:

- Hypersensitivity to alfuzosin or any of the excipients mentioned in section 6.1
- Orthostatic hypotension
- Severe liver failure (class C in the Child-Pugh classification)
- Severe kidney failure (creatinine clearance <30 mL/min)
- Concomitant administration of ritonavir alone or in combination with ombitasvir, paritaprevir, lopinavir or nirmatrelvir (see section 4.5).

4.4. Special warnings and precautions for use

Special warnings

This medicinal product must be used with caution in patients treated with antihypertensives or nitrate derivatives.

Use of this medicinal product is not recommended with antihypertensive alpha-blockers (see section 4.5).

In some subjects, orthostatic hypotension with or without symptoms (dizziness, fatigue, sweating) may develop within a few hours following administration. In such cases, the patient should lie down until the symptoms have completely disappeared.

These effects are usually transient, occur at the beginning of treatment and do not usually prevent the continuation of treatment.

Pronounced drop in blood pressure has been reported in post-marketing surveillance in patients with pre-existing risk factors (such as underlying cardiac diseases and/or concomitant treatment with anti-hypertensive medication).

There is a risk of ischemic strokes, particularly in elderly patients with pre-existing asymptomatic or symptomatic disorders of cerebral circulation (such as cardiac arrhythmia, atrial fibrillation or a history of transient ischemic attack) due to the fact that hypotension may develop following alfuzosin administration (see section 4.8).

The patient should be warned of the possible occurrence of such events.

Care should be taken, particularly in the elderly. The risk of developing hypotension and related symptoms may be greater in elderly patients.

As with all alpha-1 blockers, this medicine should be used with caution in patients with acute heart failure.

Patients with congenital prolonged QTc interval, or a history of prolonged QTc interval or who are being treated with medicines that increase the QTc interval should be monitored before and during treatment.

The combination of alfuzosin and potent CYP3A4 inhibitors (e.g. itraconazole, ketoconazole, protease inhibitors, clarithromycin, telithromycin and nefazodone) must be avoided (see section 4.5). Alfuzosin must not be used in combination with CYP3A4 inhibitors that are known to prolong the QTc interval (e.g. itraconazole and clarithromycin). If this treatment is initiated, alfuzosin treatment should be temporarily discontinued.

Rarely, alfuzosin, like other alpha-1 blockers, has been associated with priapism (persistent painful penile erection unrelated to sexual activity). Since this condition can lead to permanent impotence if not properly treated, rapid patient management (sometimes involving surgery) is essential.

Intraoperative Floppy Iris Syndrome (IFIS, a variant of small pupil syndrome) has been observed during cataract surgery in some patients on or previously treated with tamsulosin. Isolated cases have also been reported with other alpha-1 blockers; therefore, a possible class effect cannot be ruled out. Considering that IFIS can be the cause of additional technical difficulties during cataract operations, the surgeon must be informed of any history or current use of alpha-1 blockers before the eye surgery, even if the risk of IFIS occurring with alfuzosin is low.

This medicinal product contains lactose. Therefore, it is not recommended for use in patients with galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption syndrome (rare hereditary diseases).

This medicinal product contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially ‘sodium-free’.

Precautions for use

Care should be taken when alfuzosin is administered to patients who have had a pronounced hypotensive response to another alpha1-blocker.

In coronary patients, alfuzosin should not be prescribed alone. The specific treatment for coronary insufficiency should be continued. If angina pectoris reappears or worsens, alfuzosin should be discontinued.

Use with PDE5 inhibitors: concomitant administration of Xatral 2.5 mg with a phosphodiesterase type 5 inhibitor (e.g. sildenafil, tadalafil or vardenafil) can cause symptomatic hypotension in certain patients (see section 4.5). To reduce the risk of orthostatic hypotension, patients must be stabilised under alpha-blocker treatment before initiating treatment with a phosphodiesterase type 5 inhibitor.

In addition, treatment with the phosphodiesterase-type 5 inhibitor should be started at the lowest possible dose.

4.5. Interaction with other medicinal products and other forms of interaction

Drugs that induce orthostatic hypotension

In addition to antihypertensive agents, numerous drugs can cause orthostatic hypotension. These include nitrate derivatives, phosphodiesterase type-5 inhibitors, alpha 1 receptor blockers for urological conditions, imipramine antidepressants and phenothiazine neuroleptics, dopamine agonists and levodopa.
Concomitant use could therefore increase the frequency and intensity of this adverse effect. Refer to the interactions specific to each group, with the corresponding obligations.

Contraindicated combinations

+ **Ritonavir alone or in combination with ombitasvir/paritaprevir, lopinavir or nirmatrelvir (see section 4.3).**

The combined therapy causes an increase in plasma alfuzosin concentrations due to decreased alfuzosin liver metabolism.

Inadvisable combinations

+ **Antihypertensive alpha-blockers (doxazosin, prazosin, urapidil)**

There is a risk of severe orthostatic hypotension due to an enhanced hypotensive effect.

+ **Potent CYP3A4 inhibitors (boceprevir, clarithromycin, cobicistat, erythromycin, itraconazole, ketoconazole, nelfinavir, posaconazole, ritonavir, telaprevir, telithromycin, nefazodone, voriconazole)**

There is a risk of increased plasma alfuzosin concentrations and increased undesirable effects. (See section 4.4)

Combinations requiring precautions for use

+ **Phosphodiesterase type 5 inhibitors (avanafil, sildenafil, tadalafil, vardenafil)**

There is a risk of orthostatic hypotension, particularly in elderly subjects.

Treatment should be initiated at the lowest recommended dose and adjusted gradually if necessary.

Combinations to be taken into account

+ **Antihypertensive drugs except alpha-blockers**

There is a risk of severe orthostatic hypotension due to an enhanced hypotensive effect.

+ **Dapoxetine**

There is a risk of increased undesirable effects, particularly dizziness or syncope.

+ **Blood pressure-lowering drugs**

There is a risk of enhanced hypotension, particularly orthostatic.

4.6. Fertility, pregnancy and lactation

Pregnancy and breast-feeding

The therapeutic indication does not apply to women.

It is not known whether alfuzosin is safe during pregnancy nor whether it is excreted in breast milk.

4.7. Effects on ability to drive and use machines

There are no available data on the effect of alfuzosin on the ability to drive vehicles.

Special caution must be exercised by patients who drive and use machines due to the risk of orthostatic hypotension, dizzy spells, asthenia and visual disturbances, particularly at the beginning of treatment.

4.8. Undesirable effects

Undesirable effects are classified by frequency based on the following convention: very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1 000, <1/100); rare (≥1/10 000, <1/1 000); very rare (<1/10 000); frequency not known (cannot be estimated from the available data).

	FREQUENCY			
SYSTEM ORGAN CLASS	**Common (≥1% - <10%)**	**Uncommon (≥0.1% - <1%)**	**Very rare (<0.01%)**	**Not known**
Cardiac disorders		tachycardia, palpitations	angina pectoris in patients with a history of coronary artery disorders	atrial fibrillation
Eye disorders		abnormal vision		intraoperative floppy iris syndrome
General disorders and administration site conditions	asthenia, malaise	oedema, chest pain		
Gastrointestinal disorders	nausea, abdominal pain, diarrhoea, dry mouth,	vomiting		
Hepatobiliary disorders				hepatocellular injury, hepatic cholestasis
Nervous system disorders	dizziness, vertigo, light-headedness, headache	syncope, drowsiness		ischemic stroke in patients with underlying cerebrovascular disorders
Reproductive system and breast disorders				priapism
Respiratory, thoracic and mediastinal disorders		nasal congestion		
Skin and subcutaneous tissue disorders		skin eruption, pruritus	urticaria, angioedema	

Vascular disorders	orthostatic hypotension (see section 4.4)	flushing		
Blood and lymphatic system disorders				neutropenia, thrombocytopenia

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after Authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the French national reporting system, i.e.: Agence nationale de sécurité du médicament et des produits de santé (ANSM) under "Réseau des Centres Régionaux de Pharmacovigilance" (Network of Regional Pharmacovigilance Centres) - Website: https://signalement.social-sante.gouv.fr/

4.9. Overdose

If overdose occurs, the patient should be hospitalised and kept in the supine position. Conventional treatment of hypotension should be instituted. If severe hypotension occurs, a vasoconstrictor agent that acts directly on the vascular muscle fibres can be used.

Alfuzosin is highly protein-bound and is therefore not easily dialyzable.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Alpha-blockers, ATC code: G04CA01 - G: genito urinary system and sex hormones.

Alfuzosin is an orally active quinazoline derivative. It is a selective antagonist of post-synaptic alpha-1-adrenergic receptors. In vitro pharmacological studies have confirmed that alfuzosin is selective for alpha-1-adrenergic receptors located in the prostate, bladder base and urethra.

Alpha-blockers decrease infravesical obstruction via direct action on prostatic smooth muscle. In vivo animal studies have shown that alfuzosin reduces urethral pressure, thereby lowering resistance to urine flow during micturition. A study in alert rats showed a greater effect of alfuzosin on urethral pressure than on blood pressure.

Placebo-controlled studies in patients with benign prostatic hypertrophy showed that alfuzosin:

- significantly increases urine flow by a mean of 30% in patients with a flow rate of ≤15 mL/s. This improvement is observed from the first dose
- significantly reduces detrusor pressure and increases volume, producing the desire to void
- significantly reduces the residual urine volume.

These effects lead to an improvement in irritative and obstructive urinary symptoms, with no negative effect on sexual function.

Paediatric population

Alfuzosin is not indicated for use in the paediatric population (see section 4.2).

The efficacy of alfuzosin hydrochloride was not demonstrated in 2 studies conducted in 197 patients aged between 2 and 16 years with increased detrusor pressure (≥40 cm H_2O) caused by a neurological disorder. Patients were treated with 0.1 mg/kg/day or 0.2 mg/kg/day of alfuzosin hydrochloride using adapted paediatric formulations.

5.2. Pharmacokinetic properties

Alfuzosin has a mean bioavailability of 64%. Peak plasma concentrations are reached approximately 1.5 hours after administration (with a range of 0.5 to 6 hours).

Pharmacokinetic characteristics within the therapeutic range are linear. The pharmaceutical profile is characterised by large inter-individual fluctuations.

The elimination half-life of alfuzosin is approximately 4.8 hours in healthy volunteers.

Alfuzosin is approximately 90% plasma protein bound.

Alfuzosin is extensively metabolised in the liver, with only 11% of the parent compound excreted unchanged in the urine.

The majority of the metabolites (which are inactive) are excreted in the faeces (75% to 90%).

Concomitant intake of food does not affect the pharmacokinetic pattern of the drug.

In elderly patients over 75 years of age, alfuzosin absorption is more rapid and peak plasma concentrations are higher. Bioavailability may be increased and in some patients the volume of distribution is reduced. The elimination half-life does not change.

In patients with severe liver failure, the elimination half-life is prolonged. Bioavailability is increased compared with healthy volunteers.

The volume of distribution and clearance of alfuzosin are increased in renal failure, with or without dialysis, due to an increase in the free fraction. No dose adjustment is required for patients with kidney failure whose creatinine clearance is over 30 mL/min.

The pharmacokinetic profile of alfuzosin is not affected by chronic heart failure.

5.3. Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Lactose monohydrate, microcrystalline cellulose, povidone, sodium starch glycolate (type A), magnesium stearate.

Film-coating: hypromellose, Macrogol 400, titanium dioxide.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years.

6.4. Special precautions for storage

Store the blisters in the outer packaging, in order to protect from light and moisture.

6.5. Nature and contents of container

30 tablets in (PVC/aluminium) blisters.

60 tablets in (PVC/aluminium) blisters.

90 tablets in (PVC/aluminium) blisters.

100 tablets in (PVC/aluminium) blisters.

6.6. Special precautions for disposal and other handling

No special requirements for disposal.

7. MARKETING AUTHORISATION HOLDER

Sanofi Winthrop Industrie
82 avenue Raspail
94250 Gentilly
France

8. MARKETING AUTHORISATION NUMBER(S)

- 34009 330 160-1 2: 30 film-coated tablets in (PVC/aluminium) blisters
- 34009 330 161-8 0: 60 film-coated tablets in (PVC/aluminium) blisters
- 34009 556 232-3 6: 90 film-coated tablets in (PVC/aluminium) blisters
- 34009 330 162-4 1: 100 film-coated tablets in (PVC/aluminium) blisters

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01/2026

10. DATE OF REVISION OF THE TEXT

To be filled in subsequently by the Marketing Authorisation Holder

ANNEX II

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

A.1. Name and address of the manufacturer(s) of the biological active substance(s)

Not applicable.

A.2. Name and address of the manufacturer(s) responsible for batch release

Sanofi Winthrop Industrie
30-36, avenue Gustave Eiffel
37000 Tours
France

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

List I.

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

Not applicable.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

Not applicable.

E. SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE MARKETING AUTHORISATION UNDER EXCEPTIONAL CIRCUMSTANCES

Not applicable.

F. QUALITATIVE AND QUANTITATIVE COMPOSITION IN EXCIPIENTS

Lactose monohydrate..... 61.0 mg

Microcrystalline cellulose ..... 18.0 mg

Povidone..... 4.5 mg

Sodium starch glycolate (type A)..... 3.5 mg

Magnesium stearate..... 0.5 mg

For one 90.0 mg uncoated tablet.

Hypromellose ..... 3.16 mg

Macrogol 400 ..... 0.32 mg

Titanium dioxide ..... 0.52 mg

For one 94.00 mg film-coated tablet

ANNEX IIIA

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

NATURE/TYPE OUTER PACKAGING OR IMMEDIATE PACKAGING

Outer packaging.

1. NAME OF THE MEDICINAL PRODUCT

Xatral 2.5 mg film-coated tablets

Alfuzosin hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Alfuzosin hydrochloride ..... 2.5 mg

For one film-coated tablet.

3. LIST OF EXCIPIENTS

Excipient with known effect: lactose monohydrate.

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablets. Box of 30, 60, 90 or 100.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

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

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Not applicable.

8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Store the blisters in the outer packaging, in order to protect from light and moisture.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Not applicable.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder

Sanofi Winthrop Industrie
82 avenue Raspail
94250 Gentilly
France

Operator

Sanofi Winthrop Industrie
82 avenue Raspail
94250 Gentilly
France

12. MARKETING AUTHORISATION NUMBER(S)

Marketing Authorisation No.:

13. BATCH NUMBER

Batch {number}

14. GENERAL CLASSIFICATION FOR SUPPLY

List I.

15. INSTRUCTIONS ON USE

Not applicable.

16. INFORMATION IN BRAILLE

The Decision of May 7, 2008, in application of Article R. 5121-138 of the French Public Health Code published in the Official Journal of the Republic of France of May 22, 2008 must be complied with.

17. UNIQUE IDENTIFIER - 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC: {number} [CIP code]

SN: {number} [serial number]

PICTOGRAM TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

[pictogram relative to teratogenic or fetotoxic effects]

If applicable, the pictogram mentioned in section III of Article R. 5121-139 of the French Public Health Code (teratogenic or fetotoxic effects) must appear, in accordance with the application order stipulated in the same article.

[pictogram relative to effects on the ability to drive]

The pictogram mentioned in section II of Article R. 5121-139 of the French Public Health Code (effects on the ability to drive) must comply with the application order stipulated in the same article.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

NATURE/TYPE BLISTERS/STRIPS

Blisters (PVC/Alu).

1. NAME OF THE MEDICINAL PRODUCT

Xatral 2.5 mg film-coated tablets

Alfuzosin hydrochloride

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Sanofi Winthrop Industrie

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

Batch {number}

5. OTHER

Not applicable.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

NATURE/TYPE SMALL IMMEDIATE PACKAGING UNITS

Not applicable.

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Not applicable.

2. METHOD OF ADMINISTRATION

Not applicable.

3. EXPIRY DATE

Not applicable.

4. BATCH NUMBER

Not applicable.

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

Not applicable.

6. OTHER

Not applicable.

ANNEX IIIB

Package Leaflet: INFORMATION FOR THE USER

Name of the medicine

Xatral 2.5 mg film-coated tablets

Alfuzosin hydrochloride

Boxed text

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 Xatral 2.5 mg film-coated tablets are and what they are used for

Pharmacotherapeutic group - ALPHA-BLOCKERS - ATC code: G04CA01 - G: genito urinary system and sex hormones

Xatral contains alfuzosin. This medicine belongs to a group of medicines called alpha-blockers. It has an effect on the bladder, the tube which takes urine outside of the body (the urethra) and the prostate.

Xatral is used when your prostate increases in size (benign prostatic hyperplasia) to make it easier to urinate.

This medicine is for use in men only.

2. What you need to know before you take Xatral 2.5 mg film-coated tablets

Do not take Xatral 2.5 mg film-coated tablets:

- If you are allergic to the active substance (alfuzosin) or any of the other ingredients of this medicine listed in section 6.
- If you have orthostatic hypotension (drop in blood pressure when standing up, possibly with dizziness and/or fainting).
- If you have a serious liver disease (liver failure) or a serious kidney disease (severe kidney failure).
- If you are taking ritonavir alone or in combination with ombitasvir/paritaprevir, lopinavir or nirmatrelvir. See below, in the section “Other medicines and XATRAL 2.5 mg, film-coated tablets”.

Warnings and precautions

Talk to your doctor or pharmacist before taking Xatral 2.5 mg film-coated tablets.

Before beginning treatment, inform your doctor if you have heart disease (particularly if you have angina pectoris, acute heart failure or heart rhythm problems) or if you have ever experienced a significant drop in blood pressure with another medicine from the same group of medicines as Xatral (alpha-blockers).

During treatment

Orthostatic hypotension (drop in blood pressure when standing up) may develop in the first few hours after taking the medicine and be accompanied by dizziness, tiredness or sweating.

If this occurs, lie down until these symptoms, which are temporary, completely wear off, and contact your doctor.

This effect is seen particularly in elderly patients or patients who are also taking medicine to treat high blood pressure or nitrate derivatives (medicines used for angina pectoris).

This medicine must be used with caution in patients with blood flow problems in the brain, particularly elderly patients.

Contact your doctor immediately if you experience painful prolonged erection.

You should avoid using this medicine in combination with medicines used to treat high blood pressure (antihypertensives such as doxazosin, prazosin and urapidil) (see section "Other medicines and Xatral 2.5 mg film-coated tablets").

If you are going to have eye surgery (on a cataract) tell your ophthalmologist before the operation if you have recently been or are currently being treated with Xatral. This medicine can have an effect on the pupil (intraoperative floppy iris syndrome) that may lead to complications during surgery.

However, if the surgeon is warned in advance, he or she will take the necessary precautions.

Other medicines and Xatral 2.5 mg film-coated tablets

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

You must not take this medicine in combination with ritonavir alone or in combination with lopinavir (usually used for the treatment of HIV), or with ritonavir in combination with ombitasvir/paritaprevir (usually used for the treatment of chronic hepatitis C infection) or with ritonavir in combination with nirmatrelvir (usually used for the treatment of mild to moderate COVID-19).

You should avoid taking this medicine in combination with certain medicines used to treat

- high blood pressure (antihypertensives such as doxazosin, prazosin and urapidil)
- hepatitis C (e.g. telaprevir, boceprevir)
- some fungal infections (e.g. itraconazole, posaconazole)
- Cushing's syndrome (when the body produces too much cortisol), orally-administered ketoconazole
- some bacterial infections (e.g. clarithromycin, erythromycin, telithromycin)
- depression, such as nefazodone (see section "Warnings and precautions").

Xatral 2.5 mg film-coated tablets with food and drink

Not applicable.

Pregnancy and breast-feeding

This medicine is not intended for use in women.

Driving and using machines

You must take care if you drive a vehicle or use machines. This medicine can cause a significant drop in blood pressure when standing up, along with dizziness, tiredness or vision disorders, especially at the start of treatment.

Xatral 2.5 mg film-coated tablets contain a type of sugar (lactose) and sodium.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take Xatral 2.5 mg film-coated tablets

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

Posology

The usual dose is 1 tablet three times daily.

Your doctor will tell you how long you should take the medicine for.

Your doctor may need to adjust your dose if:

- You are over 65 years of age
- You have high blood pressure
- Your liver does not work properly.

Method of administration

This medicine must be swallowed whole with a glass of water.

Use in children

Xatral must not be taken by children aged between 2 and 16 years.

If you take more Xatral 2.5 mg film-coated tablets than you should

Talk to your doctor or go to accident and emergency immediately.

If you forget to take Xatral 2.5 mg film-coated tablets

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

If you stop taking Xatral 2.5 mg film-coated tablets

Not applicable.

4. Possible side effects

Like all medicines, Xatral 2.5 mg film-coated tablets can cause side effects, although not everybody gets them.

Common side effects:

- Light-headedness, dizzy spells, dizziness, fainting, significant drop in blood pressure when standing up from a lying position (see section "Warnings and precautions"), headache
- Nausea, stomach pain or diarrhoea, dry mouth
- Tiredness.

Uncommon side effects:

- Drowsiness, syncope (sudden loss of consciousness)
- Vision disorders
- Accelerated heart rate, palpitations
- Nasal congestion or runny nose (rhinitis)
- Outbreak of spots on the skin or itching
- Swelling, chest pain
- Redness of the face
- Vomiting.

Very rare side effects:

- Chest pain in patients with angina pectoris
- Hives (red itchy patches on the skin), sudden swelling of an organ, the face and/or the neck that can make it difficult to breathe and be life-threatening to the patient (angioedema).

Other possible side effects (frequency not known):

- Liver disease (hepatitis), particularly due to biliary tract obstruction
- Painful, prolonged erection
- Floppy pupil during cataract surgery (see section "Warnings and precautions")
- Irregular heartbeat (atrial fibrillation)
- Decreased number of white blood cells (neutropenia)
- Decreased number of platelets (thrombocytopenia)
- Stroke (not enough blood flow to the brain).

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 French national reporting system, i.e. *Agence nationale de sécurité du médicament et des produits de santé* (ANSM) under *"Réseau des Centres Régionaux de Pharmacovigilance"* (Network of Regional Pharmacovigilance Centres) - Website: https://signalement.social-sante.gouv.fr/

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

5. How to store Xatral 2.5 mg film-coated tablets

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 box.

Store the blisters in the outer packaging, in order to protect from light and moisture.

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 Xatral 2.5 mg film-coated tablets contain

- The active substance is:

Alfuzosin hydrochloride ..... 2.5 mg

For one film-coated tablet.

- The other ingredients are: lactose monohydrate, microcrystalline cellulose, povidone, sodium starch glycolate (type A), magnesium stearate.

  Film-coating: hypromellose, Macrogol 400, titanium dioxide.

What Xatral 2.5 mg film-coated tablets look like and contents of the pack

This medicine is supplied as film-coated tablets.

Box of 30, 60, 90 or 100 tablets.

Marketing Authorisation Holder

Sanofi Winthrop Industrie
82 avenue Raspail
94250 Gentilly
France

Operator

Sanofi Winthrop Industrie
82 avenue Raspail
94250 Gentilly
France

Manufacturer

Sanofi Winthrop Industrie
30-36 avenue Gustave Eiffel
37000 Tours
France

Names of the medicinal product in the Member States of the European Economic Area

Not applicable.

This leaflet was last revised in:

[To be filled in subsequently by the Marketing Authorisation Holder]

Other

Detailed information about this medicine is available on the ANSM website (France).