Package leaflet: Information for the patient

Obgemsa 75 mg film-coated tablets
vibegron

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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 Obgemsa is and what it is used for

Obgemsa contains the active substance vibegron. It is a bladder muscle relaxant (a beta-3 adrenergic receptor agonist) which reduces the activity of an overactive bladder and treats the related symptoms.

Obgemsa is used to treat the symptoms of an overactive bladder in adults, such as:
- a sudden need to empty your bladder (called urgency)
- having to empty your bladder more than usual (called increased urinary frequency)
- not being able to control when to empty your bladder and wetting yourself (called urge urinary incontinence)

2. What you need to know before you take Obgemsa

Do not take Obgemsa
- if you are allergic to vibegron or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking Obgemsa:
- if you have trouble emptying your bladder or you have a weak urine stream, or if you are taking any other medicines for the treatment of overactive bladder syndrome, such as anticholinergic medicines for example oxybutynin, diphenhydramine, solifenacin.

If you have severe liver problems or if you have an end-stage kidney disease as Obgemsa should not be used in these cases.

Children and adolescents
Do not give this medicine to children and adolescents under the age of 18 years because the safety and efficacy of Obgemsa in this age group has not yet been established.

Other medicines and Obgemsa
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Tell your doctor if you use digoxin (a medicine for heart failure or abnormal heart rhythm). Blood levels of this medicine are measured by your doctor. If the blood level is out of range, your doctor may adjust the dose of digoxin.
Tell your doctor if you use dabigatran etexilate (an anticoagulant agent), apixaban (an anticoagulant agent) or rivaroxaban (an antithrombotic agent). These medicines may require dose adjustments by your doctor.

Pregnancy and breast-feeding

Women of childbearing potential
If you think that you may be pregnant or planning to have a baby, you should not take Obgemsa. This is because it is not known how this medicine will affect the foetus.

Pregnancy
If you are pregnant, you should not take Obgemsa. This is because it is not known how this medicine will affect the baby.

Breast-feeding
It is likely that this medicine passes into breast milk, but the risks for the baby are unknown. Therefore, you should not breast-feed while taking Obgemsa.

Driving and using machines
Obgemsa has no or negligible influence on the ability to drive or use machines.

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

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

3. How to take Obgemsa

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 for this medicine is 1 tablet per day.

Swallow the tablet with a glass of water. If needed, the tablet can be crushed and mixed with 1 tablespoon (about 15 mL) of soft food (e.g. applesauce). Eat the mixture and drink a glass of water afterwards. Once mixed in food, the mixture should be eaten immediately. You may take your tablet with or without food.

If you take more Obgemsa than you should
If you have taken too many tablets, contact your doctor, pharmacist or hospital for advice immediately. If someone else accidentally takes your tablets, contact your doctor, pharmacist or hospital for advice immediately. Symptoms of overdose may include troubles in digestive system, headache and difficulty breathing.

If you forget to take Obgemsa
If you miss a dose, take the next dose as normal on the next day. Do not take a double dose to make up for a forgotten tablet. If you miss several doses, tell your doctor and follow the advice given to you.

If you stop taking Obgemsa
Do not stop treatment with Obgemsa early if you do not see an immediate effect. Your bladder might need some time to adapt and you should continue taking your tablets.

Do not stop taking Obgemsa when your symptoms improve, as stopping treatment may cause symptoms of overactive bladder syndrome to return. Talk to your doctor before you stop taking Obgemsa.

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.

An uncommon side effect (may affect up to 1 in 100 people) is the inability to empty your bladder (urinary retention). Obgemsa may increase the probability of not being able to empty your bladder, especially if you have bladder outlet obstruction or take other medicines for treatment of overactive bladder. Tell your doctor straight away if you are unable to empty your bladder.

Other side effects include:

Common side effects (may affect up to 1 in 10 people)
- headache
- diarrhoea
- nausea (feeling sick)
- constipation
- urinary tract infection (infection of structures that carry urine)
- residual urine volume increased (an increase in the amount of urine left in the bladder after a voluntary urination)

Uncommon side effects (may affect up to 1 in 100 people)
- hot flush
- urinary retention, including urinary straining (inability to empty your bladder)
- rash (including itchy rash, and red rash)

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 Yellow Card Scheme Website: https://yellowcard.mhra.gov.uk/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 Obgemsa

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

This medicine does not require any special storage conditions.

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 Obgemsa contains

- The active substance is vibegron. Each film-coated tablet contains 75 mg of vibegron.
- The other ingredients are:
  - Tablet core: mannitol, microcrystalline cellulose, croscarmellose sodium, hydroxypropylcellulose, and magnesium stearate. See section 2 “Obgemsa contains sodium”.
  - Film-coating: indigo carmine aluminium lake (E132), hypromellose, iron oxide yellow (E172), lactose, titanium dioxide (E171), and triacetin. See section 2 “Obgemsa contains lactose”.

What Obgemsa looks like and contents of the pack

Obgemsa are light green oval film-coated tablets (tablets), debossed with V75 on one side and plain on the other side. Tablet dimension is approximately 9 mm (length) x 4 mm (width) x 3 mm (height).

Obgemsa is available in white plastic, square or round bottles with a child-resistance plastic closure. Pack sizes: 7, 30 or 90 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
PIERRE FABRE LIMITED
250 Longwater Avenue,
Green Park,
Reading. RG2 6GP
United Kingdom

Manufacturer
PATHEON FRANCE
40 boulevard de Champaret
38300 Bourgoin Jallieu
France

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