6. Contents of the pack and other information

What Revatio looks like and contents of the pack

Revatio film-coated tablets are white and round in shape. The tablets are marked with “REVIE” on one side and “NYT 22” on the other. The tablets are provided in blister packs containing 60 tablets.

Drug Tariff Information

Store in a refrigerator at 2° to 8°C.

Do not use this medicine after the expiry date which is stated on the bottle.

Oral Suspension

Do not store above 30°C. Store in the original package in order to protect from moisture.

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

Do not use this medicine after the expiry date which is stated on the carton after EXP.

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

2. Using a mortar and pestle, crush these 62 tablets, 2–10 tablets at a time, into a fine (final concentration 10 mg/ml). The other ingredients are:

- Glycerol triacetate
- Tricalcium phosphate
- Sodium phosphate, citric acid, antifoam emulsion and is preserved with methylparaben and potassium sorbate.

3. Cap bottle and shake vigorously for a minimum of 30 seconds.

4. Measure 90 ml Ora-Sweet (clear pink liquid) allowing time for any air bubbles to dissipate.

5. Put an ancillary label on the bottle warning “Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency, should not take this medicine”. The ancillary label should also indicate “Shake well for a minimum of 10 seconds before each dosing”. Include the patient’s name, dosing instructions, expiry date, and drug name.

6. Consider the person to whom you have compounded the product that any remaining medication following completion of therapy must be disposed by either affixing an ancillary label to the bottle or adding a statement to the pharmacy label instructions.

7. Place an appropriate expiration date label according to storage conditions below.

8. Put an appropriate dose label containing instructions on storage and administration in a yellow card scheme. For dosing, round to the nearest minute of oral suspension.

9. Put an ancillary label on the bottle warning: “Do not inhale any suspended particles. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects listed in this leaflet or other information leaflets or patient information leaflets that you have been given. See section 4. Possible side effects. You can also report side effects directly (see details below).” By reporting side effects you can help provide more information on the safety of this medicine.

10. Other sources of information

- Before using this medicine, read the information leaflet that comes with it. If you do not get the information leaflet, ask your pharmacist for another copy.

- Reporting of side effects

- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects listed in this leaflet or other information leaflets or patient information leaflets that you have been given. See section 4. Possible side effects. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

- Unbd Kingdom

www.mhra.gov.uk/yellowcard

- United Kingdom

e-mail: medsafety@hpra.ie.

- Malta

Website: www.medicinesauthority.gov.mt

- e-mail: postlicensing.medicinesauthority@gov.mt

- Other sources of information

www.AdvUro.com

- Information for patients

- Information for medical or healthcare professionals only

- Compounding Instructions for a Pharmacist:

5. Add a part (15–20 mg equivalent) of Ora-Plus from step 4 to the meter and mix into this thick homogenous paste. Mix Ora-Plus from step 4 may be added if necessary.

6. Use the prepared paste as an amber glass or high density polyethylene (HDPE) bottle

7. 1 ml in 5 ml syringe

8. Use a glass oral dosing syringe for each patient.

• The active substance is sildenafil. Each tablet contains 20 mg of sildenafil (as the citrate).

• Other ingredients are:

- Tablet core: microcrystalline cellulose, calcium hydrogen phosphate (anhydrous), lactose monohydrate, magnesium stearate.

- Film coat: hypromellose, titanium dioxide (E171), lactose monohydrate, polyethylene glycol 6000.

• What Revatio looks like and contents of the pack

Revatio film-coated tablets are white and round in shape. The tablets are marked with “REVIE” on one side and “NYT 22” on the other. The tablets are provided in blister packs containing 60 tablets.

• Marketing Authorisation Holder and Manufacturer

Manufacturer:

Fareva Amboise, Zone Industrielle, 29 route des Industries, 37230 Pocé-sur-Cisse, France.

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

Contact information

Phone limited: +33 (0)2 47 23 33 11

Website: www.medicinesauthority.gov.mt

e-mail: postlicensing.medicinesauthority@gov.mt

5. How to store Revatio

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

Tablets

Do not use this medicine after the expiry date which is stated on the carton after EXP.

Do not store above 30°C. Store in the original package in order to protect from moisture.

Oral Suspension

Do not use this medicine after the expiry date which is stated on the bottle.

Store in a refrigerator at 2°C to 8°C.

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.

Do not use this medicine after the expiry date which is stated on the bottle containing the formulation prepared: 60 tablets.

To cast off and shake vigorously for a minimum of 30 seconds.

To transfer the content from the bottle to the tube with the squeezer and squeeze again.

1. Place the tube in a suitable material following completion of therapy must be discarded by either affixing an ancillary label to the bottle or adding a statement to the pharmacy label instructions.

2. Place an appropriate expiration date label according to storage conditions below.

3. For dosing, round to the nearest minute.

4. Measure 90 ml Ora-Sweet (clear pink liquid) allowing time for any air bubbles to dissipate.

5. Measure 9 ml Ora-Plus (cloudy white liquid) allowing time for any air bubbles to dissipate.

6. Rinse the mortar and pestle with the remaining Ora-Plus from step 4 and transfer rinses to the bottle to ensure complete transfer of the paste.

7. Measure 90 ml Ora-Sweet (clear pink liquid) allowing time for any air bubbles to dissipate.

8. Transfer approximately 1/2 the volume of the Ora-Sweet from step 8 to the bottle containing the formulation prepared: 60 tablets.

9. Cap bottle and shake vigorously for a minimum of 30 seconds.

10. Transfer the remaining Ora-Sweet from step 7 to the bottle and shake again vigorously.

11. Place the tube in a suitable material following completion of therapy must be discarded by either affixing an ancillary label to the bottle or adding a statement to the pharmacy label instructions.

12. Place an appropriate expiration date label according to storage conditions below.

13. For dosing, round to the nearest minute.

14. Measure 90 ml Ora-Sweet (clear pink liquid) allowing time for any air bubbles to dissipate.

15. Transfer the content from the bottle to the tube with the squeezer and squeeze again.

6. Contents of the pack and other information

Revatio contains:

- The active substance is sildenafil. Each tablet contains 20 mg of sildenafil (as the citrate).

- Other ingredients are:

- Tablet core: microcrystalline cellulose, calcium hydrogen phosphate (anhydrous), lactose monohydrate, magnesium stearate.

- Film coat: hypromellose, titanium dioxide (E171), lactose monohydrate, polyethylene glycol 6000.

1. Using a mortar and pestle, crush these 62 tablets, 2–10 tablets at a time, into a fine (final concentration 10 mg/ml). The other ingredients are:

- Glycerol triacetate
- Tricalcium phosphate
- Sodium phosphate, citric acid, antifoam emulsion and is preserved with methylparaben and potassium sorbate.

2. Compounding of an extemporaneously prepared oral suspension from Revatio 20 mg tablets uses Ora-Sweet and Ora-Plus diluents.

3. Compounding of the Revatio oral suspension from Revatio 20 mg tablets uses Ora-Sweet and Ora-Plus diluents.

4. Compounding of the Revatio oral suspension from Revatio 20 mg tablets uses Ora-Sweet and Ora-Plus diluents.

5. Compounding of an oral suspension, by a pharmaceutical, following this procedure, will provide the patient with enough medication for a 30-day course of treatment (11 ml being volumes of suspension prepared from the tablets)

6. Compounding of the Revatio oral suspension from Revatio 20 mg tablets uses Ora-Sweet and Ora-Plus diluents.

7. Compounding of the Revatio oral suspension from Revatio 20 mg tablets uses Ora-Sweet and Ora-Plus diluents.

8. Compounding of the Revatio oral suspension from Revatio 20 mg tablets uses Ora-Sweet and Ora-Plus diluents.

9. Compounding of the Revatio oral suspension from Revatio 20 mg tablets uses Ora-Sweet and Ora-Plus diluents.

10. Compounding of the Revatio oral suspension from Revatio 20 mg tablets uses Ora-Sweet and Ora-Plus diluents.

11. Compounding of the Revatio oral suspension from Revatio 20 mg tablets uses Ora-Sweet and Ora-Plus diluents.

12. Compounding of the Revatio oral suspension from Revatio 20 mg tablets uses Ora-Sweet and Ora-Plus diluents.

13. Compounding of the Revatio oral suspension from Revatio 20 mg tablets uses Ora-Sweet and Ora-Plus diluents.

14. Compounding of the Revatio oral suspension from Revatio 20 mg tablets uses Ora-Sweet and Ora-Plus diluents.

15. Compounding of the Revatio oral suspension from Revatio 20 mg tablets uses Ora-Sweet and Ora-Plus diluents.

16. Compounding of the Revatio oral suspension from Revatio 20 mg tablets uses Ora-Sweet and Ora-Plus diluents.

17. Compounding of the Revatio oral suspension from Revatio 20 mg tablets uses Ora-Sweet and Ora-Plus diluents.
2. What you need to know before you take Revatio

What is in this leaflet

This leaflet contains important information for you. Read all of this leaflet carefully before you start taking this medicine because it includes any possible side effects not listed in this leaflet. See section 4.

3. How to take Revatio

If you get any side effects, talk to your doctor or pharmacist.

• Do not give this medicine to children below 1 year of age.

• If you experience any of the following side-effects you should stop taking Revatio and contact your doctor immediately (see also section 2):

• If you have recently had a stroke, a heart attack or if you have severe liver disease or very low blood pressure.

• If you are allergic (hypersensitive) to sildenafil or any of the other ingredients of this medicine.

• If you have a disease that causes swelling in your breathing tubes due to blood clots (e.g. pulmonary embolism) or cancer of the blood cells.

• If you have high blood pressure in the blood vessels in the lungs.

• If you have blood clots in blood vessels in the lungs rather than a blocked or narrow artery.

• If you have an abnormality of red blood cells (sickle cell anaemia), cancer of blood cells or any disease or deformity of the veins.

• If you have a problem with the pumping chambers of your heart.

• If you have a disease due to a blocked or narrow vein in the lungs rather than a blocked or narrow artery.

• If you have a disease that affects your heart muscle (cardiomyopathy).

• If you experience sudden decrease or loss of vision,stop taking Revatio and contact your doctor immediately (see also section 2):

• If you have any further questions, ask your doctor or pharmacist.

4. Possible side effects

All medicines can cause side effects, although not everybody gets them. If you experience any of the following side-effects you should stop taking Revatio and contact a doctor and pharmacist (see section 2):