PATIENT INFORMATION LEAFLET

APPROVED
RP Equity Regulatory.
Sign: ..... Date: 17 Sept 2019

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

PASER GRANULES 4 g delayed-release granules

p-Aminosalicylic acid

Read all of this leaflet carefully before you start taking PASER GRANULES

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- PASER GRANULES has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT PASER GRANULES CONTAINS

- The active substance is p-aminosalicylic acid. Each packet contains 4 g p-aminosalicylic acid.
- The other ingredients are colloidal silicon dioxide, dibutyl sebacate, Eudragit L-30D, hydroxypropyl methylcellulose, microcrystalline cellulose, and talc.
- PASER GRANULES is sugar free.

2. WHAT PASER GRANULES IS USED FOR

PASER GRANULES is used to treat resistant tuberculosis (TB) in combination with other medicines. It is used in patients with Multi-drug Resistant TB (MDR-TB) or in situations in which therapy with isoniazid and rifampicin is not possible due to a combination of resistance and/or intolerance.

3. BEFORE YOU TAKE PASER GRANULES

Do not take PASER GRANULES:

- if you are hypersensitive (allergic) to p-aminosalicylic acid or any of the other ingredients of PASER

GRANULES

- if you have severe kidney disease
- if you have severe liver disease

Take special care with PASER GRANULES:

Some medical conditions may affect PASER GRANULES. Tell your doctor if any of the following applies to you:

- if you have kidney disease
- if you have a stomach ulcer
- if you have G6PD deficiency
- if you have decreased liver function. Patients with liver disease may not tolerate PASER GRANULES as well as normal patients.
- if you suffer from certain nutritional problems, such as Vitamin B_{12} deficiency, iron deficiency or malabsorption syndrome. PASER GRANULES may make these deficiencies worse. If you take PASER GRANULES for longer than one month you may need to take a vitamin B_{12} supplement.
- if you suffer from goitre problems.

PASER GRANULES may affect certain laboratory test results. Make sure lab personnel and your doctors know you use PASER GRANULES.

Diabetes patients: PASER GRANULES may cause incorrect test results with some urine ketone tests. Check with your doctor as your dose may have to be adjusted.

DO NOT USE PASER GRANULES if the packets are swollen or the granules have lost their tan colour and are dark brown or purple.

The skeletons of the granules may be seen in your stool. Do not be alarmed – this is normal.

Taking PASER GRANULES with food and drink:

To take PASER GRANULES, you should sprinkle the granules on acidic foods such as apple sauce or

yoghurt or swirl it in a fruit juice such as tomato or orange juice. This will protect the coating.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking PASER GRANULES.

Because there are no adequate and well controlled studies in humans, PASER GRANULES should not be given to a pregnant woman.

The active ingredient in PASER GRANULES is excreted in breast milk. If you are taking PASER GRANULES, you should not breastfeed your baby.

Driving and using machinery:

PASER GRANULES has not been studied for ability to drive and use machines. However, some of PASER GRANULES side effects, such as sluggish movement or vision changes, may affect your ability to drive.

Using other medicines with PASER GRANULES:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

PASER GRANULES may reduce the metabolism of isoniazid (another anti-TB agent). PASER GRANULES may also reduce the absorption of digoxin (used in the treatment of heart problems).

4. HOW TO TAKE PASER GRANULES

Do not share medicines prescribed for you with any other person.

Always take PASER GRANULES exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of PASER GRANULES is too strong or too weak, talk to your doctor or pharmacist.

Adults:

The usual dose is 4 grams (one packet) three times per day

Children:

Your doctor will decide on the dose for your child. For infants, children and adolescents the dosage will be adapted to the patient's weight, at 150 mg/kg twice or thrice daily, to a maximum daily dose of 12 g.

Instructions on taking PASER GRANULES:

- Sprinkle the granules on acidic food (e.g. apple sauce, yoghurt) or mix with tomato or orange juice. Ask your doctor if you are unsure whether you can take PASER GRANULES with a certain food or drink.
- If you mix PASER GRANULES in juice and the granules sink to the bottom, swirl the juice to mix the granules before taking it. You must take the granules within 2 hours of mixing.
- Do not chew the granules.
- Do not use PASER GRANULES if the packet is swollen or if the granules have lost their tan colour and have turned dark brown or purple. Inform your healthcare professional or pharmacist immediately and return the medication.
- Take PASER GRANULES regularly to receive the most benefit from it. Taking PASER GRANULES at the same time each day will help you remember to take it.

Duration of treatment:

Your doctor will tell you how long your treatment with PASER GRANULES will last. Do not stop using PASER GRANULES without checking with your doctor.

It is important to use PASER GRANULES for the full course of treatment. Failure to do so may decrease the effectiveness of PASER GRANULES. It will also increase the risk that your treatment will fail.

If you take more PASER GRANULES than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take PASER GRANULES:

If you miss a dose of PASER GRANULES, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for

a forgotten individual dose.

Effects when treatment with PASER GRANULES is stopped:

If you do not take PASER GRANULES as prescribed by your doctor, treatment of your TB will fail. Furthermore, the TB bacteria may develop resistance to this and certain other antibiotics.

5. POSSIBLE SIDE EFFECTS

PASER GRANULES can have side effects. Not all side effects reported for PASER GRANULES are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PASER GRANULES, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking PASER GRANULES and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Rash, hives, itching, difficulty in breathing, tightness in the chest, swelling of the mouth, face, lips, throat or tongue (allergic reactions).
- Dark urine, yellowing of the eyes and skin, fever (hepatitis).

Other side effects are:

Frequent side effects:

- Diarrhoea, nausea, stomach pain, vomiting
- Skin redness or rash

Less frequent side effects:

- Anaemia, reduction in numbers of red or white blood cells, iron- or Vitamin B_{12} deficiencies causing the following symptoms:
  - fatigue, fainting, weakness, drowsiness, dizziness, pins and needles feeling in hands and feet
  - red sore tongue, mouth ulcers,
  - confusion, mental or mood changes
  - headache
  - fast or irregular heartbeat, tremors

- pale skin

- Changes in cholesterol levels
- Thyroid gland problems
- Hearing and seeing things that are not there (hallucinations)
- Bloating, abnormally foul-smelling or loose stools, severe right-sided stomach pain (steatorrhoea)
- Fever
- Crystals in urine
- Joint pain, lower back pain
- Reduction in blood platelets, red spots on the skin, prolonged bleeding, unusual bruising or bleeding
- Yellowing of the skin and whites of the eyes (jaundice)
- Sore throat or chills
- Loss of appetite, weight loss
- Low levels of blood sugar. Symptoms include sweating, shakiness, weakness, extreme hunger, dizziness, headache, blurred vision, fast heartbeat, feeling anxious.
- Sluggish movement or speech
- Tender of painful lymph nodes (lymphadenopathy), sweating
- Vision changes
- Chest pain, shortness of breath

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF PASER GRANULES

Store at or below 25 °C.

Avoid excessive heat. DO NOT USE the packet if it is swollen or the granules have lost their tan colour, turning dark brown or purple.

Do not store in the bathroom.

Keep all medicines out of the reach and sight of children.

Do not use after the expiry date stated on the carton.

Any unused granules after initially opening the sachet must be discarded.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF PASER GRANULES

Carton of 30 packets. The packets are white, opaque and consist of paper, aluminium and LDPE layers. Each packet contains 4 grams p-aminosalicylic acid.

8. IDENTIFICATION OF PASER GRANULES

Light tan coloured, spherical shaped, odourless, and tasteless coated granules.

9. REGISTRATION NUMBER/REFERENCE NUMBER

45/20.2.3/0037

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Equity Pharmaceuticals (Pty) Ltd.

100 Sovereign Drive, Route 21 Corporate Park

Nellmapius Drive

Irene - Pretoria

Tel. no: +27 12 345 1747

11. DATE OF PUBLICATION

Date of Registration: 05 August 2011

Date of latest revision of the text: 17 September 2019

Melanie Nieuwoudt

From: Preminet (Pty) Ltd <admin@preminet.co.za>
Sent: Saturday, 17 April 2021 2:25 PM
To: Telanie Venter; Jeanne Mare
Cc: Melanie Nieuwoudt; Ilze Slabbert; Marlienka Cloete; Charlene Snyman
Subject: Draft 1 PQR-REY-150/200 mg-Caps_2019-2020 (Rev Per 01 May 2019 to 30 April 2020) for review and finalisation
Attachments: Draft 1 PQRBMST-001_BMS PQR Reyataz 150_200 mg.docx

Dear Telanie /Jeanne

Please find herewith Draft 1 for the PQR for Reyataz Capsules (Rev Per 01 May 2019 – 30 April 2020) for your review and finalisation.

<u>There are a few sections that Equity has to comment on and to complete the information:</u>

1) Section I, point No. 06 (Equity RA Dept)

2) Section I, point No. 08 (Equity QA to send query to BMS - discrepancy between BMS EXM APQR and APQR) for amount of PQCs reported (internal and external)

3) Section II, point No. 01 (Equity QA to insert missing Date of Receipt for a batch that was received in this review period)

4) Section II, point No. 04 (Equity QA to insert QAA information for local agreements with sites listed on the Registration Certificates for Reyataz Capsules)

Kind regards,

Helena van Schalkwyk