

QuadroFER

Iron Supplement

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Unscheduled

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

QUADROFER mouth-dispersible stick packs (sachets)

Read all of this leaflet carefully because it contains important information.

QUADROFER is available without a doctor's prescription, for you to treat iron deficiency. Nevertheless, you still need to use QUADROFER carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share QUADROFER with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 14 days.

1. WHAT QUADROFER CONTAINS:

Sorbitol, Sideral® r.m. -Sucrosomial® Iron (21 mg/stickpack) (iron pyrophosphate, pregelatinised rice starch, sucrose esters) of fatty acids, sunflower lecithin on glucose syrup carrier, milk proteins, tricalcium phosphate, xylitol, vitamin C (L ascorbic acid), flavours, citric acid, vitamin D3 (cholecalciferol, medium chain triglycerides, arabic gum, sucrose, starch, DL-alpha-tocopherol, tricalcium phosphate), vitamin B12 (cyanocobalamin, citric acid, maltodextrin, trisodium citrate), sucralose and acesulfame K, vitamin B6 (pyridoxine hydrochloride), folic acid (pteroyl-monoglutamic acid).
Gluten free.

Contains sweeteners: sorbitol 1130, 688 mg; xylitol 160 mg; sucralose 0,896 mg; acesulfame K 0,576 mg.
Contains **milk proteins**.
Lactose free.

2. WHAT QUADROFER IS USED FOR

QUADROFER for the normal formation of red blood cells and haemoglobin.

QUADROFER is a preparation of iron that is conveyed inside a sucrosomial® membrane and is therefore highly available for absorption.

Sucrosomial® technology protects oral and gastrointestinal mucosa from the oxidising action of iron, therefore avoiding metallic taste, gastric discomfort, mucous tissue and stool staining.

In fact, the iron contained in QUADROFER never comes in contact with the mucous tissues of the body; therefore, it presents a high degree of gastrointestinal tolerability reducing the risk of gastrointestinal irritation.

3. BEFORE YOU TAKE QUADROFER

This medicine has not been evaluated by the South African Health Products Regulatory Authority. This medicine is not intended to diagnose, treat, cure or prevent any disease.

Do not take QUADROFER:

- If you are hypersensitive (allergic) to QUADROFER or any of the other ingredients of QUADROFER (see the section explaining what QUADROFER contains).
- If you are uncertain if this applies to you, please discuss this with your doctor or pharmacist before taking QUADROFER.

Take special care with QUADROFER:

- Talk to your doctor before taking or whilst taking Quadrofer
- if you are hypersensitive (allergic) to iron preparations.

Taking QUADROFER with food and drink:

Directly disperse one stick pack (sachet) of QUADROFER in the mouth with or without food.

Pregnancy and Breastfeeding:

QUADROFER is safe to use during pregnancy and lactation. If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other health care professional for advice before taking QUADROFER.

Driving and using machinery:

QUADROFER is not expected to have an effect on your ability to drive or operate machinery.

Important information about some of the ingredients of QUADROFER:

QUADROFER contains sweeteners (sorbitol, xylitol, sucralose and acesulfame). If you have been told that you have an intolerance to some sweeteners, you should not take QUADROFER.

Using other medicines with QUADROFER:

Always tell your healthcare professional if you are taking any other products (this includes complementary or traditional medicines).

4. HOW TO TAKE QUADROFER

Do not share medicines prescribed for you with any other person.
Take one stick pack (sachet) a day directly dispersed in the mouth, or as recommended by a doctor.

Do not exceed the recommended daily dose.

You should check with your doctor or pharmacist if you are unsure.

If you have the impression that QUADROFER is too strong or too weak, tell your doctor or pharmacist.

If you take more QUADROFER than you should:

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

If you stop taking QUADROFER:

If you stop taking Quadrofer your original symptoms may return.

5. POSSIBLE SIDE EFFECTS

QUADROFER can have side effects.

Not all side-effects reported for QUADROFER are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Quadrofer, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF QUADROFER

- Store in the original packaging at or below 30 °C.
- Avoid exposure to localised heat sources, direct sunlight and contact with water.
- Do not use QUADROFER after the expiry date printed on the label or carton. The expiry date refers to the product unopened and properly stored.
- Return any expired or unused products to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

7. PRESENTATION OF QUADROFER

30 mouth-dispersible PET-ALU-PE sticks (sachets) of 1,6g each, packed in a carton.

8. IDENTIFICATION OF QUADROFER

QUADROFER is a mouth-dispersible ivory white powder.

9. REGISTRATION NUMBER

TBA

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Austell Pharmaceuticals (Pty) Ltd, 1 Sherborne Road Parktown, Johannesburg, 2193, Tel: 0860 287 385

11. DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET

16 May 2018

PHARMANUTRA

Produced and packaged in the production facility based Via Castellana, 2 - 39036 Mereto di Tomba (UD) Italy on behalf of: PharmaNutra S.p.A. Via Campodavola 1, 56122 Pisa (Italy) www.pharmanutra.it

Austell

Applicant/Applikant: Austell Pharmaceuticals (Pty) Ltd, 1 Sherborne Rd, Parktown, Johannesburg, 2193
Customer care/Klientediens: 0860 287 385
www.austell.co.za

Sideral
SUCROSOMIAL® IRON
16 G x 30



Rev. 7 of 11.23