Package leaflet: Information for the patient

ARCALION® 200 Sulbutiamine

treatment for asthenia in all its forms

Read all of this leaflet carefully before you start taking this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet?

1. WHAT ARCALION 200 mg, coated tablet IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group: Vitamin B1, plain, ATC code: A11DA02
This medicine is indicated in certain transient adult (+ 15 years) fatigue conditions.
You must talk to your doctor if you do not feel better or if you feel worse after 4 weeks.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ARCALION 200 mg, coated tablet

If your doctor has informed you of an intolerance to certain sugars, please contact him/her before taking this medicine.

Do not take ARCALION 200 mg, coated tablet:
· If you are allergic to sulbutiamine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
This medicinal product contains lactose, glucose and sucrose. This medicine should not be used by patients with glucose and glactose malabsorption syndrome (rare hereditary diseases), glactose intolerance, Lapp lactase deficiency or a sucrose/isomaltase deficiency or fructose intolerance.
This medicine contains an azo colouring agent (E110) and may provoke allergic reactions (see section 4 "Possible side effects").

If symptoms persist for more than 4 weeks, consult your physician.
Talk to your doctor, pharmacist or nurse before taking ARCALION 200 mg, coated tablet.

Children and adolescents
ARCALION should not be used in children and adolescents.

Other medicines and ARCALION 200 mg, coated tablet
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. ARCALION may interact with the following medicines:
· diuretics (used for treatment of high blood pressure), which may increase the thiamine urinary excretion (Vitamin B1, derived from sulbutiamine)
· neuromuscular blocking agents (used in general anesthesia) whose effects may be increased with thiamine (Vitamin B1, derived from sulbutiamine)

ARCALION 200 mg, coated tablet, with food, drinks and alcohol
Not applicable.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
The use of ARCALION should generally be avoided during pregnancy. Tell your doctor if you think your are pregnant.

Breastfeeding
You should not take ARCALION if you are breast-feeding. Tell your doctor immediately if you are breast-feeding or about to start breast-feeding.

Driving and using machines
Not applicable.

ARCALION 200 mg, coated tablet contains: glucose, lactose, sunset yellow FCF aluminum lake (E110) and sucrose.

3. HOW TO TAKE ARCALION 200 mg, coated tablet

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
FOR ADULT USE ONLY
2 to 3 tablets a day.
Tablets should be swallowed whole with a large glass of water, dividing the doses between the morning and midday meals.
Duration of treatment is limited to 4 weeks.
Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Method of administration
Oral route.

Duration of treatment
Do not use for more than 4 weeks.

If you take more ARCALION 200 mg, coated tablet than you should:
In case of overdose, the symptoms may include agitation and limb tremors.
Contact immediately your doctor or pharmacist.

If you forget to take ARCALION 200 mg, coated tablet
Not applicable

if you stop taking ARCALION 200 mg, coated tablet
Not applicable
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS?

Like all medicines, ARCALION 200 mg, coated tablet can cause side effects, although not everybody gets them.

The following side effects have been observed:
Uncommon (may affect up to 1 in 100 patients but more than 1 in 1,000)
· cutaneous eruption,
· nausea, vomiting,
· agitation,
· headaches
· tremor,
· malaise.

Not known (frequency cannot be estimated from the available data)
· stomach pain, diarrhoea.
Due to the presence of Sunset Yellow FCF, risk of allergic reaction.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to company website https://www.servier.com.pk/ or Drug Regulatory Authority of Pakistan http://dra.gov.pk/
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ARCALION 200 mg, coated tablet

Keep out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the outer packaging. The expiry date refers to the last day of that month.

Blister: the tablets must not be stored above 25ºC.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

What ARCALION 200 mg, coated tablet contains

- The active substance is:

Sulbutiamine 200 mg For one coated tablet

- The other ingredients are:
Maize starch, starch paste, anhydrous glucose, lactose monohydrate, magnesium stearate, talc, sodium hydrogen carbonate, carmellose sodium, white beeswax, titanium dioxide (E 171), ethyl cellulose, sunset yellow FCF aluminum lake (E 110), glycerol monooleate, polysorbate 80, povidone, sucrose, colloidal anhydrous silica (Aerosil 130).

What is ARCALION 200 mg, coated tablet and contents of the pack
This medicinal product is available in the form of coated tablets. Box of 20 coated tablets.

7. MARKETING AUTHORISATION HOLDER

HEAD OFFICE
SERVIER RESEARCH & PHARMACEUTICALS [PAKISTAN] (PVT) LTD
65 MAIN BOULEVARD GULBERG LAHORE PAKISTAN

PLANT:
SERVIER RESEARCH & PHARMACEUTICALS [PAKISTAN](PVT)LTD
9 KM SHEIKHPURA ROAD LAHORE PAKISTAN.

8. MARKETING AUTHORISATION NUMBER(S)

014463

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SERVIER

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