

# SERC<sup>®</sup> 8 mg TABLETS / SERC<sup>®</sup> 16 mg TABLETS

## (Betahistine dihydrochloride)

Your medicine is known by the above two names, but will be referred to as Serc<sup>®</sup> Tablets throughout this leaflet.

### 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 becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### In this leaflet:

1. What Serc<sup>®</sup> Tablets are and what they are used for
2. Before you take Serc<sup>®</sup> Tablets
3. How to take Serc<sup>®</sup> Tablets
4. Possible side effects
5. How to store Serc<sup>®</sup> Tablets
6. Further information

### 1. WHAT SERC<sup>®</sup> TABLETS ARE AND WHAT THEY ARE USED FOR

Serc<sup>®</sup> Tablets contain betahistine. This medicine is called a histamine analogue. It is used to treat:

- dizziness (vertigo)
- ringing in the ears (tinnitus)
- hearing loss suffered by people with Ménière's disease

This medicine works by improving blood flow in the inner ear. This lowers the build up of pressure.

### 2. BEFORE YOU TAKE SERC<sup>®</sup> TABLETS

#### Do not take Serc<sup>®</sup> Tablets if:

- You are allergic to any of the ingredients in the tablets (see section 6 for further details).
- You have high blood pressure due to an adrenal tumour (phaeochromocytoma).

If any of the above applies to you, do not take this medicine and talk to your doctor.

#### Take special care and tell your doctor if:

- you have a stomach ulcer
- you have asthma
- you are pregnant or planning to become pregnant
- you are breast-feeding

If any of the above applies to you, talk to your doctor before taking this medicine. Your doctor will tell you whether it is safe for you to start taking this medicine. Your doctor may also want to monitor your asthma while you take Serc<sup>®</sup> Tablets.

#### Taking other medicines

Please tell your doctor or pharmacist if you are taking or have taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Anti-histamines – these may (in theory) lower the effect of Serc<sup>®</sup> Tablets. Also, Serc<sup>®</sup> Tablets may lower the effect of anti-histamines.
- Monoamine-oxidase inhibitors (MAOIs) – used to treat depression or Parkinson's disease.

These may increase the exposure of Serc<sup>®</sup> Tablets.

#### Taking Serc<sup>®</sup> Tablets with food and drink

You can drink alcohol whilst taking Serc<sup>®</sup> Tablets.

You can take Serc<sup>®</sup> Tablets with or without food.

#### Pregnancy and breast-feeding

Do not take Serc<sup>®</sup> Tablets if you are pregnant unless your doctor has decided that it is absolutely necessary. Ask your doctor for advice.

Do not breast-feed while using Serc<sup>®</sup> Tablets unless instructed by your doctor. It is not known if Serc<sup>®</sup> Tablets passes into breast milk.

#### Driving and using machines

You can drive and use machines while you are taking this treatment, so long as this medicine does not make you sleepy. Make sure you know how this medicine affects you before you drive or use machines.

### 3. HOW TO TAKE SERC<sup>®</sup> TABLETS

#### How to take Serc<sup>®</sup> Tablets

- Swallow the tablets with water.
- Take the tablet with or after a meal.

#### How many Serc<sup>®</sup> Tablets to take

Always follow your doctor's instructions because your doctor might adjust your dose.

- Serc<sup>®</sup> Tablets are available in two strengths an 8 mg tablet and a 16 mg tablet.
- The usual starting dose is 16 mg three times a day (48 mg).
- Your doctor may lower your dose to 8 mg three times a day (24 mg).

Keep taking your tablets. The tablets can take a while to start to work.

Serc<sup>®</sup> Tablets are not recommended for use in those under 18 years old.

#### How to stop taking Serc<sup>®</sup> Tablets

Keep taking your tablets until your doctor tells you to stop.

Even when you start feeling better, your doctor may want you to carry on taking the tablets for some time to make sure that the medicine has worked completely.

#### If you take more Serc<sup>®</sup> Tablets than you should

If you or someone else takes too many Serc<sup>®</sup> Tablets (an overdose), talk to your doctor or go to a hospital straight away. Take this medicine pack with you.

#### If you forget to take Serc<sup>®</sup> Tablets

If you miss a tablet, wait until the next dose is due. Do not try to make up for the dose you have missed.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines Serc<sup>®</sup> Tablets can cause side effects (unwanted effects or reactions), but not everyone gets them.

#### The following serious side effects may occur during treatment with Serc<sup>®</sup> Tablets:

- Allergic reactions such as :
- swelling of your face, lips, tongue or neck.

This may cause difficulty breathing.

- a red skin rash, inflamed itchy skin.

#### If any of the side effects occur you should stop treatment immediately and contact your doctor.

#### Common side effects (at least 1 in 100 and less than 1 in 10 patients):

Nausea, indigestion.

#### Other side effects

Headache, itching, rash, hives, mild gastric complaints such as vomiting, stomach pain and bloating. Taking Serc<sup>®</sup> Tablets with food can help reduce any stomach problems.

If any of the side effects becomes serious, or if you notice any side effects that are not listed in this leaflet, please tell your doctor or pharmacist.

### 5. HOW TO STORE SERC<sup>®</sup> TABLETS

- Do not store above 25°C. Store in the original package.
- **Keep out of the sight and reach of children.**
- Do not use this medicine after the expiry date (This is printed on the carton or blister label).
- If your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine, if your doctor tells you to.
- If your tablets show signs of deterioration or discolouration, you should seek the advice of your pharmacist who will tell you what to do.

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 Serc® Tablets contains

Each tablet contains 8 mg or 16 mg of the active ingredient betahistine dihydrochloride.

The tablets also contain the following inactive ingredients: microcrystalline cellulose, mannitol, citric acid monohydrate, colloidal anhydrous silica and talc.

### What Serc® Tablets look like and the contents of the pack

Serc® 8mg Tablets are round, flat bevelled-edged, white uncoated tablets marked '256' on one side, and imprinted 'S' above an inverted arrow on the reverse.

Serc® 16mg Tablets are round, white biconvex tablets marked '267' either side of a deep scoreline on one side, and imprinted 'S' above an inverted arrow on the reverse.

Serc® 8mg Tablets are available as blister packs of 60 tablets.  
Serc® 16mg Tablets are available as blister packs of 30 tablets.

### Who manufactured your medicine

Serc® Tablets are manufactured by Abbott Healthcare SAS., Route de Belleville – Lieu-dit-'Maillard', 01400 Chatillon-sur-Chalaronne, France. Procured from within the EU and repackaged by the Product Licence Holder: Beachcourse Limited, 20 Alliance Court, Alliance Road, London W3 0RB.

Serc® 8 mg Tablets	PL 16378/0405	<b>POM</b>
Serc® 16 mg Tablets	PL 16378/0406	

Revision date: 25.09.2012

Leaflet reference: SERC 8/16/UT

# BETAHISTINE DIHYDROCHLORIDE 8 mg TABLETS / BETAHISTINE DIHYDROCHLORIDE 16 mg TABLETS

Your medicine is known by the above two names, but will be referred to as Betahistine Tablets throughout this leaflet.

## 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 becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### In this leaflet:

1. What Betahistine Tablets are and what they are used for
2. Before you take Betahistine Tablets
3. How to take Betahistine Tablets
4. Possible side effects
5. How to store Betahistine Tablets
6. Further information

## 1. WHAT BETAHISTINE TABLETS ARE AND WHAT THEY ARE USED FOR

Betahistine Tablets contain betahistine. This medicine is called a histamine analogue. It is used to treat:

- dizziness (vertigo)
- ringing in the ears (tinnitus)
- hearing loss suffered by people with Ménière's disease

This medicine works by improving blood flow in the inner ear. This lowers the build up of pressure.

## 2. BEFORE YOU TAKE BETAHISTINE TABLETS

### Do not take Betahistine Tablets if:

- You are allergic to any of the ingredients in the tablets (see section 6 for further details).
- You have high blood pressure due to an adrenal tumour (phaeochromocytoma).

If any of the above applies to you, do not take this medicine and talk to your doctor.

### Take special care and tell your doctor if:

- you have a stomach ulcer
- you have asthma
- you are pregnant or planning to become pregnant
- you are breast-feeding

If any of the above applies to you, talk to your doctor before taking this medicine. Your doctor will tell you whether it is safe for you to start taking this medicine. Your doctor may also want to monitor your asthma while you take Betahistine Tablets.

### Taking other medicines

Please tell your doctor or pharmacist if you are taking or have taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Anti-histamines – these may (in theory) lower the effect of Betahistine. Also, Betahistine may lower the effect of anti-histamines.
- Monoamine-oxidase inhibitors (MAOIs) – used to treat depression or Parkinson's disease.

These may increase the exposure of Betahistine.

### Taking Betahistine Tablets with food and drink

You can drink alcohol whilst taking Betahistine Tablets.

You can take Betahistine Tablets with or without food.

### Pregnancy and breast-feeding

Do not take Betahistine Tablets if you are pregnant unless your doctor has decided that it is absolutely necessary. Ask your doctor for advice.

Do not breast-feed while using Betahistine Tablets unless instructed by your doctor. It is not known if Betahistine Tablets passes into breast milk.

### Driving and using machines

You can drive and use machines while you are taking this treatment, so long as this medicine does not make you sleepy. Make sure you know how this medicine affects you before you drive or use machines.

## 3. HOW TO TAKE BETAHISTINE TABLETS

### How to take Betahistine Tablets

- Swallow the tablets with water.
- Take the tablet with or after a meal.

### How many Betahistine Tablets to take

Always follow your doctor's instructions because your doctor might adjust your dose.

- Betahistine Tablets are available in two strengths an 8 mg tablet and a 16 mg tablet.
- The usual starting dose is 16 mg three times a day (48 mg).
- Your doctor may lower your dose to 8 mg three times a day (24 mg).

Keep taking your tablets. The tablets can take a while to start to work.

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### How to stop taking Betahistine Tablets

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### The following serious side effects may occur during treatment with Betahistine Tablets:

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This may cause difficulty breathing.

- a red skin rash, inflamed itchy skin.

**If any of the side effects occur you should stop treatment immediately and contact your doctor.**

### Common side effects (at least 1 in 100 and less than 1 in 10 patients):

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### Other side effects

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