PATIENT INFORMATION LEAFLET

Sinthrome® Tablets 1mg
acenocoumarol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you
• 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
• If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

The information in this leaflet has been divided into the following sections:
1. What Sinthrome is and what it is taken for
2. What you need to know before you take Sinthrome
3. How to take Sinthrome
4. Possible side effects
5. How to store Sinthrome
6. Contents of the pack and other information

1. What Sinthrome is and what it is taken for

Sinthrome belongs to a group of medicines called anticoagulants (blood thinning medicines).

Sinthrome is used to treat and prevent blood clots blocking the blood vessels e.g. deep vein thrombosis (DVT).

Sinthrome does not dissolve blood clots that have already formed but it may stop the clots from becoming larger and causing more serious problems.

2. What you need to know before you take Sinthrome

Follow all the doctor’s instructions carefully. They may differ from the general information contained in this leaflet.

Do not take Sinthrome:
• if you are allergic (hypersensitive) to acenocoumarol, any other medicines that you have taken to thin your blood or to any of the ingredients in Sinthrome (see Section 6 Contents of the pack and other information)
• if you are pregnant, planning to become pregnant or breast-feeding
• if you are an alcoholic
• if you have any mental illness for example, schizophrenia or dementia
• if you have recently had, or are about to have an operation on your spine, brain, eyes or any major surgery
• if you have had a stroke caused by bleeding into your brain
• if you suffer from very high blood pressure
• if you have a stomach ulcer or any intestinal bleeding
• if you pass blood in your water or cough up blood
• if you suffer from any bleeding disorders, bleeding problems or unexplained bruising
• if you have pericarditis or endocarditis – inflammation or infection around the heart which causes pain in the chest
• if you have severe liver or kidney disease
• if you regularly drink cranberry juice or take cranberry extracts.

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you take Sinthrome.

Take special care with Sinthrome
Before you take Sinthrome tell your doctor or pharmacist:
• if you have cancer
• if you have an infection or inflammation (swelling)
• if you have a disorder affecting the absorption of food from the stomach and/or intestine
• if you have heart failure (which causes swelling and shortness of breath)
• if you have liver or kidney problems
• if you have an overactive thyroid
• if you are elderly
• if you suffer from a blood disorder such as protein C or protein S deficiency – this would cause you to bleed for longer than normal after a cut or injury.

You should not receive any injections into your muscles whilst you are taking Sinthrome.

If you need any injections into your spine or as part of a scan or X-ray test or if you need minor surgery, including dental surgery, make sure you discuss your treatment with your doctor first.

If you are involved in an accident while on Sinthrome you are likely to bleed more than normal. The doctor or hospital staff must be informed that you are taking Sinthrome immediately. Always carry your personal anticoagulation card (an identification card from your pharmacist stating that you are using this medicine).

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you take Sinthrome.

Taking other medicines
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription (over-the-
counter). This applies especially to the following medicines as they may interfere with Sinthrome:

**Medicines that increase the activity of Sinthrome such as:**

- heparin - to thin the blood in the treatment of deep vein thrombosis, blood clots or after surgery
- Salicylic acid and related substances (e.g. Acetyl salicylic acid, aminosalicylic acid, diflunisal) (medicine used against pain)
- Clopidogrel, ticlopidine, phenylbutazone or other pyrazolone derivatives (sulfinpyrazone), other non-steroidal anti-inflammatory agents (medicines affecting the function of platelets (particles in the blood involved in blood clotting)).

When Sinthrome is prescribed in combination with these drugs, more frequent monitoring (including blood tests) will be needed.

**Other medicines that may increase the activity of Sinthrome such as:**

- allopurinol or sulfinpyrazone - for the treatment of gout and to lower uric acid levels
- anabolic steroids - used as replacement therapy
- androgens such as testosterone and mesterolone - used as replacement therapy
- anti-arrhythmic agents such as amiodarone and quinidine - medicines for an irregular heartbeat
- antibiotics (e.g. erythromycin, tetracyclines, neomycin, chloramphenicol, amoxicillin, some cephalosporins, some fluoroquinolones)- medicines used against infections
- selective serotonin re-uptake inhibitors such as fluoxetine and paroxetine - used to treat anxiety and depression
- paracetamol – a medicine used for pain
- sulfonamides such as co-trimoxazole - used to treat infections
- sulphonylureas such as
- clofibrate and related substances - medicines used against high cholesterol
- corticosteroids such as prednisolone and methylprednisolone - steroids used to treat inflammatory bowel disease, arthritis and certain skin conditions
- disulfiram - for alcohol dependence
- etacrynic acid or thiazide diuretics (“water tablets”) such as bendroflumethiazide or metolazone - for water retention or high blood pressure
- glucagon - used to treat low blood sugar levels
- imidazole derivatives (e.g. metronidazole, and even when administered locally, miconazole) - a medicine used against infection
- tramadol - a strong pain killer
- tamoxifen - for breast cancer and fertility
- azathioprine - for organ transplantation, chronic inflammatory and autoimmune diseases
- proton pump inhibitors (e.g. omeprazole)
- plasminogen activators (e.g.
tolbutamide, chlorpropamide and glibenclamide - oral medicines for diabetes

- thyroid hormones such as levothyroxine - used to treat an underactive thyroid

- statins and other lipid lowering drugs such as fenofibrate, simvastatin or colestyramine - used to lower blood cholesterol levels

- antineoplastics such as mercaptopurine and 5-fluorouracil - for breast, gastrointestinal and skin cancer

- H₂-agonists such as cimetidine or ranitidine - used to treat stomach or intestinal ulcers

Medicines that may decrease the effect of Sinthrome such as:

- aminoglutethimide - used to treat cancer or Cushing’s syndrome

- protease inhibitors such as ritonavir or indinavir - used to treat HIV

- barbiturates such as sodium amytal or Phenobarbital and carbamazepine - for epilepsy or to help you sleep

- corticosteroids (high-dose intravenous methylprednisolone, prednisolone) - medicines used to treat inflammation

- oral contraceptives such as Femodene, Logynon and Cilest - for birth control

- rifampicin - medicine used against infection

- St John’s Wort - for depression

- cholestyramine - medicine used against high cholesterol levels

- griseofulvin - used to treat fungal infections

Effects of Sinthrome on other medicines

- Sinthrome may increase the risk of toxicity by hydantoin derivatives such as phenytoin - medicines used to treat epilepsy

Taking with food and drink

Be careful when drinking alcohol as it may affect how Sinthrome thins your blood. Check with your doctor first.

You should avoid drinking cranberry juice or taking other cranberry products, such as capsules or concentrates as this could mean you do not receive the correct amount of acenocoumarol.
**Elderly**
If you are 65 years or older you may be more sensitive to the effects of Sinthrome and so need more frequent check-ups. You may also need lower doses.

**Children and adolescents**
Experience with Sinthrome in children and adolescents is limited and so these patients need more frequent check-ups.

**Pregnancy and breast-feeding**
Do not take Sinthrome if you are pregnant. Sinthrome, like other anticoagulants can cause serious harm to your baby. Tell your doctor if you are pregnant or trying to become pregnant. Your doctor will discuss with you the potential risk of taking Sinthrome during pregnancy.

The decision to breast-feed while taking Sinthrome should be carefully considered with your doctor. You and your child may require blood tests if you are breast-feeding while you are taking Sinthrome. However, as a precaution, your doctor should prescribe vitamin K to your child to prevent their blood from being thinned.

If you are of child bearing age, a pregnancy test may be done by your doctor to rule out pregnancy before you are given Sinthrome. You may also be asked to use birth control while taking Sinthrome.

Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**
Sinthrome has no influence on the ability to drive or use machines.

Sinthrome tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor or pharmacist before taking this medicinal product.

### 3. How to take Sinthrome

Always take Sinthrome exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are not sure.

Sinthrome should be taken as a single dose at the same time every day. Swallow your tablets whole with a drink of water.

Your doctor will arrange regular blood tests during treatment with Sinthrome to check on how fast your blood is clotting. This will help the doctor decide on your dose.

The dose of Sinthrome will vary from patient to patient and from day to day. The following can be used as a guide:
Adults and elderly:
The usual starting dose is between 2 mg/day to 4 mg/day without administration of a loading dose. Treatment can be started with a loading dose regimen, usually 6 mg on the first day followed by 4 mg on the second day.

Elderly patients, patients with liver disease or severe heart failure or malnourished patients may need lower doses.

Children:
Sinthrome is not recommended for children.

Tell your doctor or dentist or pharmacist at every visit that you are using Sinthrome.

What to do if you take more Sinthrome than you should
If you accidentally take too many tablets, or someone else takes any of your medicine, you should tell your doctor immediately or contact the nearest accident and emergency department. You may require blood tests to monitor your condition and treatment may be required. Show any left-over medicines or the empty packet to the doctor.

If you forget to take Sinthrome
Do not worry. If you forget to take a dose, take it as soon as possible, unless it is almost time to take the next dose. Do not take a double dose. Then go on as before.

If you have any questions about stopping Sinthrome, talk to your doctor.

4. Possible side effects

Like all medicines, Sinthrome can cause side effects, although not everyone gets them.

If you get any of the following, tell your doctor or pharmacist:
Common (may affect up to 1 in 10 people):
• unusual bleeding such as:
  - bleeding from the gums
  - unexplained bruising or nosebleeds
  - heavy periods
  - heavy bleeding from cuts or wounds
• signs of bleeding inside the body such as:
  - stomach or abdominal pain
  - backache
  - blood in the urine
  - bloody or black tarry stools
  - coughing or vomiting blood
  - dizziness
  - severe headache
- joint pain or stiffness
- blurred sight.

Rare (may affect up to 1 in 1000):
- allergic reaction in the form of skin rash, or itching
- skin rashes
- itching
- unexplained fever
- loss of appetite
- feeling or being sick
- unusual hair loss.

Very rare (may affect up to 1 in 10,000):
- bruising with blistering of the skin with or without scars, usually in areas of:
  - thighs
  - buttocks
  - abdomen
  - breast
  - or sometimes in the toes
- bruising or bleeding under the skin (possible sign of vasculitis)
- jaundice (possible signs of liver injury).

Tell your doctor or pharmacist if you think you have any of these or other problems with Sinthrome:

5. How to store Sinthrome

Keep out of the reach and sight of children.

Do not take Sinthrome after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

If your doctor decides to stop your treatment, return any unused medicine to the pharmacist. Only keep it if your doctor tells you to.

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

6. Contents of pack and other information

What Sinthrome contains
The active substance is acenocoumarol 1mg. This is the new name for nicoumalone. The ingredient itself has not changed.
The other excipients are: aerosol 200 (silica aerogel), lactose, hypromellose, magnesium stearate, maize starch and talc.
What Sinthrome looks like and contents of the pack
Sinthrome tablets are white, round, flat tablets, with “CG” imprinted on one side and “AA” on the other. They come in cartons of 100 tablets.

Marketing Authorisation Holder and Manufacturer
Novartis Pharmaceuticals UK Ltd, Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR, United Kingdom.

The information in this leaflet applies only to Sinthrome. If you have any questions or you are not sure about anything, ask your doctor or a pharmacist.

This leaflet was last revised in October 2014

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