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Questions and answers on Saroten and associated names (amitriptyline)

Outcome of a procedure under Article 30 of Directive 2001/83/EC

On 23 February 2017, the European Medicines Agency completed a review of Saroten. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that there is a need to harmonise the prescribing information for amitriptyline in the European Union (EU).

What is Saroten?

Saroten is a medicine used to treat a variety of conditions in the EU, including depression and various depressive states, a number of disorders associated with chronic (long-term) pain including the prevention of migraine or recurring headaches, and for the treatment of nocturnal enuresis (bedwetting) in children. Saroten is available as modified-release capsules, tablets (including modified-release tablets), and as a solution for injection. It contains the active substance amitriptyline.

Saroten and associated names (such as Redomex and Sarotex) is marketed in Austria, Belgium, Cyprus, Denmark, Estonia, Germany, Greece, Luxembourg, the Netherlands and Sweden, and also in Norway. The companies that market these medicines include Bayer GmbH and Lundbeck A/S. Amitriptyline is also available in EU countries as generic amitriptyline.

Why was Saroten reviewed?

Saroten is authorised in the EU via national procedures. This has led to divergences across Member States in the way the medicine can be used, as seen in the differences in the summaries of product characteristics (SmPCs), labelling and package leaflets in the countries where the medicine is marketed.

On 17 December 2015, the Greek medicines regulator, the National Organization for Medicines (EOF), referred the matter to the CHMP in order to harmonise the marketing authorisations for Saroten and associated names in the EU.

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What are the conclusions of the CHMP?

The CHMP, in the light of the data submitted and the scientific discussion within the Committee, was of the opinion that the SmPCs, labelling and package leaflets should be harmonised across the EU.

The areas harmonised include:

4.1 Therapeutic indications

The CHMP agreed that Saroten and associated names could be used in adults for:

- the treatment of serious depression (major depressive disorder)
- the treatment of neuropathic pain (long-lasting pain caused by nerve damage)
- treatment to prevent chronic tension-type headache (CTTH)
- treatment to prevent migraine.

While harmonising the use of Saroten in neuropathic pain and prevention of CTTH and migraine, the CHMP considered that Saroten should not be used for other forms of chronic pain.

The Committee agreed that the medicine could also be used in children from 6 years of age to treat nocturnal enuresis. It should only be prescribed by a specialist doctor and should only be used when physical causes of the problem (including conditions such as spina bifida) have been ruled out and when other treatments, including other medicines used for this problem, have not worked.

4.2 Posology and method of administration

The CHMP harmonised the doses to be used in the approved indications. Treatment is usually by mouth and the dose depends on the condition to be treated; as the strengths of the different tablets and capsules can vary, it is important to choose one that allows the right dose to be given. Treatment for depression or chronic pain may take 2 to 4 weeks to start to work, and treatment for depression should be continued for up to 6 months after the patient gets better. For initial treatment in hospital patients, Saroten can also be given as an injection into a muscle or a drip (infusion) into a vein.

The medicine should not be given to children to treat depression or pain. For the treatment of bedwetting the dose is given an hour to an hour-and-a-half before bedtime and a course of treatment should last for a maximum of 3 months.

4.3 Contra-indications

Saroten must not be used in patients who are hypersensitive (allergic) to the medicine or any of its ingredients. It must also not be used in patients who have recently had a heart attack or have disorders of the electrical activity or rhythm of the heart or reduced blood flow to the heart muscle, nor in those with severe liver disease. Use is not permitted in children less than 6 years of age.

Patients must not receive treatment with certain other medicines called monoamine oxidase inhibitors (MAOIs) at the same time as Saroten, and there should be a gap (usually of two weeks) between stopping one of these medicines and starting Saroten, or vice versa.

Other changes

The CHMP harmonised other sections of the SmPC including the warnings and precautions relating to treatment (4.4), and recommendations not to use the medicine during pregnancy and to consider the

risks and benefits of use during breast feeding (4.6). Other amendments included the information on interactions with other medicines (4.5), and the list of side effects (4.8).

The amended information to doctors and patients is available here.

The European Commission issued a decision on this opinion on 08/05/2017.