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EMA starts review of ipidacrine-containing medicines

Review will evaluate effectiveness in authorised uses and liver safety

EMA's human medicines committee (CHMP) has started a review of medicines containing ipidacrine. These medicines have been authorised in several EU countries through national procedures and are used in adults to treat different conditions affecting the nervous system.

A company recently submitted an application for a generic formulation of ipidacrine in four EEA countries. In the context of this application, concerns were raised regarding the strength of the data supporting the effectiveness of ipidacrine in its authorised uses. This was because these data mainly came from studies which had several uncertainties. Many of these studies included a small number of participants, did not compare ipidacrine to another medicine or placebo (a dummy treatment), or were designed so that both the participants and investigators conducting the studies were aware of the treatment that was given. In addition, the findings of a study comparing ipidacrine with placebo for the treatment of lumbosacral radiculopathy (a condition where the nerves in the lower back are irritated or compressed) contributed to the uncertainties regarding its effectiveness[1].

Furthermore, medicines containing ipidacrine are authorised for use in a diverse range of neurological conditions, with differing causes and symptoms, which are not clearly defined or aligned with current guidelines issued by medicines regulators.

Concerns were also raised regarding the potential for ipidacrine to cause liver damage. This followed reports of increased levels of liver enzymes compared to those recorded before treatment, in a study with a generic formulation of ipidacrine. A study in animals also contributed to the uncertainty regarding the effects of ipidacrine on liver safety.

EMA will now review all available data on the safety and effectiveness of ipidacrine-containing medicines and make a recommendation on whether their marketing authorisations should be maintained, varied, suspended or withdrawn across the EU.

[1] https://www.clinicaltrialsregister.eu/ctr-search/search?query=2019-002632-90

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More about the medicine

In the EU, ipidacrine-containing medicines are used in adults to treat several conditions affecting the nervous system. These include diseases affecting the peripheral nervous system (the part of the nervous system outside of the brain and spinal cord) such as neuritis (inflammation of the nerves), polyneuritis (inflammation of multiple nerves), polyneuropathy (damage affecting multiple nerves), polyradiculoneuropathy (an inflammatory condition affecting the peripheral nerves and roots of the spinal nerves), myasthenia gravis (a disease that causes muscle weakness), and myasthenic syndrome (a group of conditions causing muscle weakness).

They are also used to treat:

- bulbar palsy and paresis (disorders affecting the nerves that control speech and swallowing);
- demyelinating conditions (conditions that cause the breakdown of the protective covering around nerves) together with other therapies;
- memory disorders due to different causes including Alzheimer's disease and senile dementia (decline in mental abilities that occurs in older age);
- intestinal atony (a lack of muscle contraction in the gut, resulting in problems with its movement);
- adults recovering from central nervous system lesions (damage to the tissue of the brain or spinal cord) that cause movement disorders.

Ipidacrine-containing medicines are authorised in a number of EU countries including Austria, Bulgaria, Croatia, Finland, Hungary, Latvia, Lithuania, Norway, Poland, Romania, Slovakia and Slovenia. They have been used in some of these countries since 1997 and are available as either tablets taken by mouth or as an injection given into a muscle or under the skin.

They are available under a range of trade names including Ipidacrin Md-Pharm, Ipidacrine Grindeks, Ipidacrine Hydrochloride Grindeks, Ipigriks, Ipigrix and Neiromidin.

More about the procedure

The review of ipidacrine-containing medicines has been initiated at the request of the Irish medicines regulatory agency, under Article 31 of Directive 2001/83/EC.

The review is being carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.