EMA/210708/2026
18 September 2026

EMA concludes review of ipidacrine-containing medicines

Benefits continue to outweigh risks, but important restrictions on the medicines' use are recommended.

EMA's human medicines committee (CHMP) has finalised its review of medicines containing ipidacrine, which are used in adults to treat different conditions affecting the nervous system.

The Committee recommended restricting and better defining the approved uses of the medicines. The medicines can now only be used to relieve symptoms of specific conditions leading to nerve damage in one or more nerves (mononeuropathies and polyneuropathies), but no longer for neuritis, polyneuritis, polyradiculoneuropathy and myasthenic syndrome. They can also be used for the symptomatic treatment of Alzheimer's disease and intestinal atony (a lack of muscle contraction in the gut, resulting in problems with its movement), as an additional symptomatic treatment in certain patients recovering from stroke or traumatic brain injury, and in patients with myasthenia gravis (a disease that causes muscle weakness).

In addition, the Committee recommended that the medicines should no longer be used to treat demyelinating diseases, which are conditions that damage the protective covering around nerves.

The review found that the currently authorised uses were not well defined. Many of the available studies in people with these conditions included only a small number of patients, did not compare ipidacrine with another treatment or placebo (a dummy treatment), or were conducted in a way that could have influenced the results. In some cases, standard of care had changed and no longer supported the use of ipidacrine for these types of disease.

Therefore, the Committee recommended revising approved uses of ipidacrine to align them with the available data and the current standards of care.

The CHMP also recommended that ipidacrine medicines should only be prescribed by doctors experienced in diagnosing and treating these conditions.

Based on the available safety data, the Committee did not identify any new safety concerns. However, there is an increased risk of side effects at high doses and a risk of liver toxicity cannot be excluded. Therefore, caution is recommended when using the medicine at doses greater than 80 mg per day and in patients who have or have had abnormal liver function in the past.

The full list of revised uses can be found in the published product information.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Information for patients

- Following its review, the CHMP recommended changes to the authorised uses of ipidacrine-containing medicines which should now only be used to treat symptoms of specific conditions affecting the nervous system, Alzheimer's disease and intestinal atony, as well as additional symptomatic treatment in certain patients recovering from stroke or traumatic brain injury and in patients with myasthenia gravis.
- The Committee recommended that the medicine should no longer be used for neuritis (inflammation of the nerves), polyneuritis (inflammation of multiple nerves), polyradiculoneuropathy (an inflammatory condition affecting the peripheral nerves and roots of the spinal nerves), myasthenic syndrome (a group of conditions causing muscle weakness) or demyelinating diseases (conditions that cause the breakdown of the protective covering around nerves).
- There is an increased risk of side effects at high doses of ipidacrine and a risk of liver toxicity cannot be excluded. Therefore, caution is recommended when ipidacrine is used at daily doses greater than 80 mg and in patients who have or have had liver problems.
- If you are taking ipidacrine for neuritis, polyneuritis, polyradiculoneuropathy, myasthenic syndrome or demyelinating diseases, have been prescribed a daily dose above 80 mg or have liver disease, you should contact your doctor.
- Dosing recommendations for some uses have been revised and your doctor will take these into account when prescribing the medicine to you.
- If you are taking ipidacrine and have any questions, you should speak to your doctor or pharmacist.

Information for healthcare professionals

- Following its review, the CHMP recommended changes to the authorised uses of ipidacrine-containing medicines to better reflect the available evidence and current clinical practice. The changes provide greater clarity on the conditions and patient populations for which the medicines can be used.
- The recommendations are as follows:
  - The current use in peripheral nervous system diseases (neuritis, polyneuritis, polyneuropathy, polyradiculoneuropathy, myasthenia and myasthenic syndrome of various aetiologies) has been restricted to symptomatic treatment of acquired mononeuropathies and polyneuropathies and adjunctive symptomatic treatment of myasthenia gravis.
  - The current use for bulbar palsy and paresis has been restricted to adjunctive symptomatic treatment of bulbar dysfunction during the recovery period following ischaemic stroke affecting the brainstem.
  - The current use for organic central nervous system lesions with movement disorders during the recovery period has been restricted to adjunctive symptomatic treatment of motor impairment during the recovery period following ischaemic or haemorrhagic stroke or traumatic brain injury.

  - The current use for memory disorders of various origins (Alzheimer's disease and other types of senile dementia) has been restricted to symptomatic treatment of mild to moderately severe Alzheimer's disease with or without vascular dementia.
  - The current use for intestinal atony has been restricted to symptomatic treatment of intestinal atony.
  - The current use for demyelinating diseases has been removed.
- Ipidacrine should no longer be used for neuritis, polyneuritis, polyradiculoneuropathy, myasthenic syndrome of various aetiologies and demyelinating diseases because the data were too limited to support the benefits, and standards of care had changed and no longer supported these uses of ipidacrine.
- Ipidacrine should only be prescribed by doctors experienced in diagnosing and treating these conditions.
- Dosing recommendations for some indications have been revised, and prescribers should consult the revised product information for further details.
- There is an increased risk of side effects at high doses of ipidacrine and a risk of liver toxicity cannot be excluded. Therefore, caution is recommended when using the medicine at doses greater than 80 mg per day and in patients who have or have had abnormal liver function in the past.

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).
- 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 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 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 agency, under Article 31 of Directive 2001/83/EC.

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