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Questions and answers on Haldol Decanoate and associated names (solution for injection)

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

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

What is Haldol Decanoate?

Haldol Decanoate is an antipsychotic medicine used for schizophrenia and schizoaffective disorder (schizophrenia with mood disorders), which are mental disorders that affect how the person thinks, feels or behaves.

Haldol Decanoate is given by injection into the muscle usually every 4 weeks, to patients who have been taking haloperidol by mouth.

Haldol Decanoate and associated names (such as Aloperidin Decanoas, Haldol Decanoas, Haldol Decanoat, Haldol Decanoate, Haldol Decanoato, Haldol Depot, Serenase Dekanoat, and Serenase Depot) is marketed in Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Sweden and United Kingdom, and in Iceland and Norway. It contains the active ingredient haloperidol decanoate. It is also available in the EU as generic haloperidol decanoate.

The companies that market these medicines include Janssen-Cilag Ltd and associated companies.

Why was Haldol Decanoate reviewed?

Haldol Decanoate 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.

Haldol Decanoate was identified as needing harmonisation by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh).

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On 18 June 2014, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Haldol Decanoate and associated names in the EU.

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 Haldol Decanoate injection can be used for the continuing treatment of schizophrenia and schizoaffective disorder in adults who have been on a stable dose of haloperidol by mouth.

4.2 Posology and method of administration

The CHMP has harmonised the guidance on calculating the dose of Haldol Decanoate based on the patient's dose of haloperidol by mouth. Low doses are recommended for elderly patients unless they have already been receiving higher doses of haloperidol and have not had unacceptable side effects.

4.3 Contra-indications

The CHMP agreed to harmonisation of Haldol Decanoate's contra-indications. In particular, Haldol Decanoate must not be used in patients with heart disorders such as certain heart-rhythm problems, heart failure and recent heart attack, and with central nervous depression (reduced brain activity that slows down breathing and heart rate and reduces alertness).

4.4 Special warnings and precautions

The CHMP harmonised the SmPC to include information on when Haldol Decanoate's side effects on movement might appear, details on mortality in the elderly, and effects on the heart and the brain. The SmPC recommends caution in patients who have a high level of the hormone prolactin and in those who have tumours that are worsened by prolactin.

Other changes

The CHMP harmonised other sections of the SmPC including interactions between Haldol Decanoate and other medicines (section 4.5), as well as information on pregnancy, lactation and fertility (section 4.6).

The amended information to doctors and patients is available here.

The European Commission issued a decision on this opinion on 28/04/2017.