

HUMAN MEDICINES

Key information for patients, consumers and healthcare professionals Published monthly by the European Medicines Agency



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This newsletter is addressed primarily to organisations representing patients, consumers and healthcare professionals. It provides a summary of key information relating to medicines for human use published during the previous month by the European Medicines Agency.

Information is selected based on recommendations from consulted patients, consumers and healthcare professionals, and does not necessarily cover all relevant information published by the Agency.

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You can find details on how to cancel / unsubscribe to an RSS feed on the RSS reader tool that you are using, for example Unsubscribe from an RSS Feed for users of Microsoft Outlook.

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Information on medicines

Antivirals/anti-infectives

New information on authorised medicines

Comirnaty (tozinameran / riltozinameran and tozinameran / famtozinameran and tozinameran / COVID-19 mRNA Vaccine (nucleoside modified)) - EMA recommends approval of a adapted COVID-19 vaccine targeting Omicron XBB.1.5 Prevention of COVID-19Cancer

Cancer

Withdrawal of applications for new medicines

Lutholaz (pegfilgrastim) 🌣

Intended to reduce the duration of neutropenia (low levels of neutrophils, a type of white blood cell) in cancer patients

Supply shortages

Abraxane (paclitaxel)

Treatment of different types of cancer

Methotrexate (methotrexate)

Treatment of different types of cancer

Direct Healthcare Professional Communication (DHPC)

Potential missing package leaflet in folding boxes of RoActemra (tocilizumab), Hemlibra (emicizumab), Herceptin (trastuzumab), Kadcyla (trastuzumab emtansine), MabThera (rituximab), Phesgo (pertuzumab / trastuzumab) and Tecentriq (atezolizumab)

Treatment of various conditions

Diabetes

Supply shortages

Saxenda (liraglutide)

Treatment of obesity and weight-related complications such as type 2 diabetes

Tresiba (insulin degludec)

Treatment of diabetes type 1 and 2

Victoza (liraglutide)

Treatment of diabetes type 2 in addition to diet and exercise

Hematology (blood conditions)

Direct Healthcare Professional Communication (DHPC)

Potential missing package leaflet in folding boxes of RoActemra (tocilizumab), Hemlibra (emicizumab), Herceptin (trastuzumab), Kadcyla (trastuzumab emtansine), MabThera (rituximab), Phesqo (pertuzumab / trastuzumab) and Tecentrig (atezolizumab)

Treatment of various conditions

Metabolic disorders

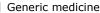
Supply shortages

Saxenda (liraglutide)

Treatment of obesity and weight-related complications such as type 2 diabetes









Nervous system

New medicines authorised

Aquipta (atogepant) Prevention of migraine

Safety update

Review of Valproate-containing medicines - EMA review of data on paternal exposure to valproate Treatment of epilepsy and bipolar disorder

Ophthalmology (eye conditions)

Withdrawal of applications for new medicines

<u>Lumevoq</u> (lenadogene nolparvovec) Intended for treatment of loss of vision due to an eye condition known as Leber hereditary optic neuropathy

Rheumatology (immune and inflammatory conditions)

Supply shortages

Methotrexate (methotrexate) Treatment of different types of inflammatory diseases

Direct Healthcare Professional Communication (DHPC)

Potential missing package leaflet in folding boxes of RoActemra (tocilizumab), Hemlibra (emicizumab), Herceptin (trastuzumab), Kadcyla (trastuzumab emtansine), MabThera (rituximab), Phesgo (pertuzumab / trastuzumab) and Tecentrig (atezolizumab)

Treatment of various conditions

Medicines under additional monitoring

Updated list of medicines under additional monitoring



Other information

Guidelines

Guidelines open for consultation

Concept paper on the development of a Reflection Paper on modern manufacturing techniques used for herbal preparations

Deadline for comments: 15 November 2023

Scientific committee and working party activities

- Medicinal products for human use: monthly figures July 2023
- CAT agendas, minutes and reports
- CHMP agendas, minutes and highlights
- COMP agendas, minutes and meetings reports
- HMPC agendas, minutes and meetings reports
- PDCO agendas, minutes and meeting reports
- PRAC agendas, minutes and highlights
- PRAC recommendations on safety signals

Other publications

- EMA's response to the COVID-19 pandemic
- EMA mourns passing of Noël Wathion

Events

Strengthening life-sciences innovation across Europe: EU-Innovation Network conference - 21 November 2023 - Agenda

Explanation of terms used

Orphan medicine

A medicine intended for the treatment of a rare, serious disease. These medicines are granted orphan status during their development; at time of approval, orphan designations are reviewed to determine whether the information available to date allows maintaining the medicine's orphan status.

ff Generic medicine

A medicine that is essentially the same as one that has already been authorised for use. (The latter is known as the 'reference medicine')

Biosimilar medicine

A biological medicine that is similar to another biological medicine which has already been authorised for use. (Biosimilar medicines are also known as 'similar biological' medicines)

Conditional approval

A medicine that fulfils an unmet medical need may, if its immediate availability is in the interest of public health, be granted a conditional marketing authorisation on the basis of less complete clinical data than are normally required, subject to specific obligations being imposed on the authorisation holder to generate complete data on the medicine.

Exceptional circumstances

A medicine may be approved in some cases where the applicant cannot provide comprehensive data on the safety or efficacy of the medicine under normal conditions of use, due to exceptional circumstances such as ethical issues or the rarity of the disease concerned. These medicines are subject to specific post-authorisation obligations and monitoring.

Medicines assessed under Article 58

Article 58 of Regulation (EC) No 726/2004 allows the <u>CHMP</u> to give opinions, in co-operation with the World Health Organization, on <u>medicinal products</u> that are intended exclusively for markets outside of the European Union.

Note on the centralised authorisation procedure

To obtain a single marketing authorisation (licence) for a medicine that is valid in all Member States of the European Union (EU) – via a process known as the 'centralised procedure' – the company or person developing the medicine must submit an application to the European Medicines Agency.

The Agency's Committee for Medicinal Products for Human Use (CHMP) carries out a scientific evaluation of the information contained in the application and prepares an opinion (scientific recommendation). The Agency transmits this (positive or negative) opinion to the European Commission, which then issues a Decision granting or refusing the marketing authorisation.

When the CHMP adopts a positive opinion on a medicine, the Agency publishes on its website a 'summary of opinion', in the first instance, followed by more detailed information in a 'European public assessment report (EPAR)' after the marketing authorisation has been granted.

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http://www.ema.europa.eu

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