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Questions and answers on the recommendation for the refusal of the marketing authorisation for Milnacipran Pierre Fabre Médicament/Impulsor

milnacipran

On 23 July 2009, the Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion, recommending the refusal of the marketing authorisation for the medicinal product Milnacipran Pierre Fabre Médicament/Impulsor, intended for the treatment of fibromyalgia in adults. The company that applied for authorisation is Pierre Fabre Medicament.
The applicant requested a re-examination of the opinion. After considering the grounds for this request, the CHMP re-examined the initial opinion, and confirmed the refusal of the marketing authorisation on 19 November 2009.

What is Milnacipran Pierre Fabre Médicament/Impulsor?
Milnacipran Pierre Fabre Médicament/Impulsor is a medicine that contains the active substance milnacipran. It was to be available as capsules.

What was Milnacipran Pierre Fabre Médicament/Impulsor expected to be used for?
Milnacipran Pierre Fabre Médicament/Impulsor was expected to be used to treat adults with fibromyalgia, a disease causing long-lasting, widespread pain and painful responses to touch. Fibromyalgia can also cause other symptoms such as tenderness, stiffness, tiredness, anxiety and changes in how the patient sleeps, feels and thinks. The cause of fibromyalgia is not known.

How was Milnacipran Pierre Fabre Médicament/Impulsor expected to work?
The active substance in Milnacipran Pierre Fabre Médicament/Impulsor, milnacipran, is a 'serotonin-noradrenaline re-uptake inhibitor'. It was expected to work by preventing the neurotransmitters 5-hydroxytryptamine (also called serotonin) and noradrenaline from being taken back up into nerve cells in the brain and spinal cord. Neurotransmitters are chemicals that allow nerve cells to communicate with one another. By blocking their re-uptake, milnacipran was expected to increase the level of communication between these nerve cells. Since these neurotransmitters are involved in reducing the sensation of pain, it was expected that blocking their re-uptake into nerve cells would improve the symptoms of fibromyalgia.

What documentation did the company present to support its application to the CHMP?
The effects of Milnacipran Pierre Fabre Médicament/Impulsor were first tested in experimental models before being studied in humans. In three main studies, 2,960 adult patients with fibromyalgia were given either Milnacipran Pierre Fabre Médicament/Impulsor or placebo (a dummy treatment) for around four to seven months. The main measures of effectiveness were based on the patients perceived improvement in symptoms, particularly pain levels and their overall wellbeing.

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What were the major concerns that led the CHMP to recommend the refusal of the marketing authorisation?
The CHMP was of the opinion that the effect of the medicine was marginal. There was also a lack of data on the long-term effects in a European population. Therefore, at that point in time, the CHMP was of the opinion that the benefits of Milnacipran Pierre Fabre Médicament/Impulsor in the treatment of fibromyalgia did not outweigh its risks. Hence, the CHMP recommended that Milnacipran Pierre Fabre Médicament/Impulsor be refused marketing authorisation. The CHMP refusal was confirmed after re-examination.

What are the consequences of the refusal for patients in clinical trials or compassionate use programmes using Milnacipran Pierre Fabre Médicament/Impulsor?
The company informed the CHMP that there are currently no ongoing clinical trials with Milnacipran Pierre Fabre Médicament/Impulsor in Europe for fibromyalgia.