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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): somatropin

Procedure No. EMEA/H/C/PSUSA/00002772/202003

Period covered by the PSUR: 31/03/2017 To: 31/03/2020

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Annex I

Scientific conclusions and grounds for the variation to the terms of the Marketing Authorisation(s)

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for somatropin, the scientific conclusions of CHMP are as follows:

In view of available data on risk(s) from clinical trial(s), the literature, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge, the PRAC Rapporteur considers a causal relationship between somatropin and acute pancreatitis is at least a reasonable possibility. The PRAC Rapporteur concludes that Section 4.4 of the SmPC of products containing somatropin should be amended to add a warning on pancreatitis.

Additionally, the PRAC Rapporteur considers a causal relationship between somatropin and gynecomastia is established and concludes that section 4.8 of the SmPC of products containing somatropin should be amended, to add the adverse reaction gynecomastia with a frequency uncommon.

The Package leaflet is updated accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for somatropin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing somatropin is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.

Annex II

Amendments to the product information of the nationally authorised medicinal product(s)

Amendments to be included in the relevant sections of the Summary of Product Characteristics (new text **underlined and in bold**, deleted text ~~strike through~~)

For all MAHs, which do not have this or a similar wording:

Summary of Product Characteristics

- Section 4.4

A warning should be added as follows:

[For both adults and children]

Pancreatitis

Although rare, pancreatitis should be considered in somatropin-treated patients who develop abdominal pain, especially in children.

Amendments to be included in the relevant sections of the Package Leaflet (new text **underlined and in bold**, deleted text ~~strike through~~)

Package Leaflet

2. What you need to know before you use [product]

Warnings and precausions

Talk to your doctor before using [product]

<product name> may cause an inflammation of the pancreas, which causes severe pain in the abdomen and back. Contact your doctor if you or your child develops stomach ache after taking <product name>.

For all MAHs:

Summary of Product Characteristics

[For both adults and children]

- Section 4.8

The following adverse reaction should be added under the SOC Reproductive system and breast disorders with a frequency uncommon.

Gynecomastia

Package Leaflet

4. Possible side effects

[Frequency uncommon]

[For both adults and children]

Breast enlargement (gynaecomastia)