

Annex III

Amendments to the Summaries of Product Characteristics and Package Leaflets

Note: These amendments to the summary of product characteristics and package leaflet are valid at the time of the Commission Decision.

After the Commission Decision the National Competent Authorities will update the product information as required.

Amendments to the Summary of Product Characteristics and Package Leaflet for all somatropin medicinal products:

Summary of Product Characteristics

[...]

Section 4.3 "Contraindications"

"Somatropin must not be used when there is any evidence of activity of a tumour. Intracranial tumours must be inactive and antitumour therapy must be completed prior to starting GH therapy. Treatment should be discontinued if there is evidence of tumour growth."

[...]

Section 4.4 "Special warnings and precautions for use"

"The maximum recommended daily dose should not be exceeded (see section 4.2)."

[...]

Package Leaflet

[...]

2. Before you use <(Invented) name of the product>

Do not use <(Invented) name of the product> and tell your doctor if you have an active tumour (cancer). Tumours must be inactive and you must have finished your anti-tumour treatment before you start your treatment with <(Invented) name of the product>.