

ANNEX III

AMENDMENTS TO BE INCLUDED IN THE RELEVANT SECTIONS OF THE SUMMARY OF PRODUCTS CHARACTERISTICS AND PACKAGE LEAFLET

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.

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The following wording should be included in the SmPC of the marketing authorisations to be varied, as relevant:

Section 4.8

“Hepatitis that may be serious”

PACKAGE LEAFLET

The following wording should be included in the package leaflet of the marketing authorisations to be varied, as relevant:

SECTION 2 - BEFORE YOU TAKE [PRODUCT NAME]

“Other medicines and [Product name]”

For Orlistat 60 mg capsules:

- *“- acarbose (an anti-diabetic drug used to treat type 2 diabetes mellitus). [Product name] is not recommended for people taking acarbose.”*

For Orlistat 120 mg capsules:

“[Product name] is not recommended for people taking acarbose (an anti-diabetic drug used to treat type 2 diabetes mellitus).”

SECTION 3 – HOW TO TAKE [PRODUCT NAME]

“[Product name] can be taken immediately before, during a meal or up to one hour after a meal. The capsule should be swallowed with water.”

SECTION 4 - POSSIBLE SIDE EFFECTS

- *“Hepatitis (inflammation of the liver). Symptoms can include yellowing skin and eyes, itching, dark coloured urine, stomach pain and liver tenderness (indicated by pain under the front of the rib cage on your right hand side), sometimes with loss of appetite.”*
- *“oxalate nephropathy (build up of calcium oxalate which may lead to kidney stones). See Chapter 2, take extra care with [Product name]”*