

Sikkerhetsoppdatering

HMG-CoA-reduktasehemmere(statiner)

April 2010

Tekst til preparatomtale

SUMMARY OF PRODUCT CHARACTERISTICS

Section 4.4 – Special warnings and precautions for use

Interstitial lung disease

Exceptional cases of interstitial lung disease have been reported with some statins, especially with long term therapy (see section 4.8). Presenting features can include dyspnoea, non-productive cough and deterioration in general health (fatigue, weight loss and fever). If it is suspected a patient has developed interstitial lung disease, statin therapy should be discontinued.

Section 4.8 – Undesirable effects

The following adverse events have been reported with some statins:

- Sleep disturbances, including insomnia and nightmares [where this is not already listed]
- Memory loss
- Sexual dysfunction [where this is not already listed]
- Depression
- Exceptional cases of interstitial lung disease, especially with long term therapy (see section 4.4)

Tekst til pakningsvedlegg

PACKAGE LEAFLET

Check with your doctor or pharmacist before taking [statin] if you:

- Have severe respiratory failure

Possible side effects

- Sleep disturbances, including insomnia and nightmares
- Memory loss
- Sexual difficulties
- Depression
- Breathing problems including persistent cough and/or shortness of breath or fever