

**PhVWP report on rosuvastatin (Crestor) and risk of gynaecomastia
Agreed by PhVWP November 2011**

English wording to be implemented

SmPC

Section 4.8 Undesirable effect

Reproductive system and breast disorders

... gynaecomastia

Frequency

- Very rare

PIL

Section 4 'Possible side effects'

Gynecomastia (breast enlargement in men)

Frequency

- Very rare

PhVWP/CMD(H) vedtaget SPC og PIL ordlyd vedtaget november 2011.

Rosuvastatin (Crestor) og risiko for gynækomasti

Dansk ordlyd, der skal implementeres

SPC

Punkt 4.8 – Bivirkninger

Det reproduktive system og mammae

.....gynækomasti

Frekvens

.....meget sjælden

PIL

Punkt 4 – Bivirkninger

Gynækomasti (brystforstørrelse hos mænd)

Frekvens

.....meget sjælden