

## PhVWP/CMD(h) core wording for corticosteroids and psychiatric and systemic ADR to inhaled and intranasal steroids.

### Inhaled Corticosteroids

#### Section 4.4 of the SmPC

It is proposed that a short statement should be included in section 4.4 of the SmPC for all inhaled steroids to alert prescribers to the potential for psychological and behavioural effects (alongside any warnings on systemic side-effects)

Proposed additional wording: (**bold and underlined** below)

#### Section 4.4 (Special warnings and precautions for use)

*Systemic effects of inhaled corticosteroids may occur, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract, glaucoma, **and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children)**. It is important therefore that the dose of inhaled corticosteroid is titrated to the lowest dose at which effective control of asthma is maintained.*

#### Section 4.8 of the SmPC

For section 4.8 of the SmPC, it is proposed that psychological and behavioural side-effects should be included for all inhaled steroids amongst other listed ADRs, as follows.

#### Section 4.8 (undesirable effects)

System Organ Class	Adverse Event	Frequency
Psychiatric Disorders	<b><u>Psychomotor hyperactivity, sleep disorders, anxiety, depression, aggression, behavioural changes (predominantly in children)</u></b>	unknown*

*\*unless the MAH can designate a suitable frequency category according to the Guideline on Summary Of Product Characteristics*

#### Patient Information Leaflet

The warnings on psychological and behavioural adverse reactions in the SmPC should be reflected in the Patient Information Leaflet using suitable lay terms and with information on the rarity of these reactions, if available.

It is also proposed that a general reminder to patients not to exceed the prescribed dose should be included in the leaflet, if not already included.

#### Patient Information Leaflet

***Note:** wording for the PIL varies widely amongst products and the wording suggested below is largely based on patient-friendly wording taken from PILs which have undergone successful user-testing.*

### Section 3:

If you use more [product] than you should:

**It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should not increase or decrease your dose without seeking medical advice.**

### Section 4

*Frequency not known, but may also occur:*

**• Sleeping problems, depression or feeling worried, restless, nervous, over-excited or irritable. These effects are more likely to occur in children**

## **Intranasal corticosteroids**

### **Section 4.4 of the SmPC**

Section 4.4 of the UK SmPC for intranasal products already includes a statement on the risk of systemic side-effects, without specific examples of systemic ADRs. It is proposed to include examples of systemic ADRs to nasal steroids (including psychiatric effects) as a class effect in section 4.4, using wording which makes it clear these are less likely to occur with intranasal than oral steroids.

### **Section 4.4 (Special warnings and precautions for use)**

*Systemic effects of nasal corticosteroids may occur, particularly at high doses prescribed for prolonged periods. **These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations. Potential systemic effects may include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, cataract, glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children).***

### **Patient Information Leaflet**

The general warnings on systemic side-effects in section 4.8 of the SmPC should be reflected in the Patient Information Leaflet using suitable lay terms and with information on the rarity of these reactions. Since specific examples of effects which may occur are described in section 4.4 of the SmPC only, and are not proposed for inclusion in section 4.8, specific examples should not be included in section 4 of the Patient Information Leaflet as side-effects.

It is also proposed that a general reminder to patients not to exceed the prescribed dose should be included in the leaflet, if not already included.

### **Patient information leaflet**

*Note: wording for the PIL varies widely amongst products and the wording suggested below is largely based on patient-friendly wording taken from PILs which have undergone successful user-testing.*

### **Section 3:**

If you use more [product] than you should:

**It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should use only as much as your doctor recommends; using more or less may make your symptoms worse.**

## PhVWP/CMD(h) ordlyd for kortikosteroider og psykiske samt systemiske bivirkninger ved inhalerede og intranasale steroider.

### Inhalerede kortikosteroider

#### Pkt. 4.4 i SmPC

Foreslået tilføjet tekst: (**fed og understreget** nedenfor).

#### **Pkt. 4.4 (Særlige advarsler og forsigtighedsregler vedrørende brugen)**

*Systemisk virkning kan opstå efter inhalation af steroider, især ved høje doser givet i længere perioder, men det er langt mindre sandsynligt end ved oral steroidbehandling. Eventuel systemisk virkning kan omfatte Cushings syndrom, cushingoide træk, binyrebarksuppression, væksthæmning hos børn og unge, nedsat knogletæthed, katarakt, glaukom **og sjældnere, en række psykiske og adfærdsrelaterede bivirkninger, inklusiv psykomotorisk hyperaktivitet, søvnforstyrrelser, angst, depression eller aggression (specielt hos børn).** Det er derfor vigtigt, at dosis reduceres til den laveste effektive dosis.*

#### Pkt. 4.8 i SmPC

I pkt. 4.8 i SmPC foreslås det at psykiske og adfærdsrelaterede bivirkninger skal inkluderes for alle inhalationssteroider sammen med de andre nævnte bivirkninger, som følger:

Pkt. 4.8 (Bivirkninger)		
Systemorganklasse	Bivirkning	Frekvens
Psykiske forstyrrelser	<b><u>Psykomotorisk hyperaktivitet, søvnforstyrrelser, angst, depression, aggression, adfærdsforandringer (hovedsageligt hos børn)</u></b>	Ikke kendt*

\*Med mindre MAH kan give en passende frekvens kategori i henhold til Guideline on Summary of Product Characteristics.

### Indlægsseddel

**Bemærk:** Teksten i indlægssedler varierer meget for forskellig produkter. Teksten foreslået nedenfor er primært baseret på patient-venlige tekster taget fra indlægssedler, der har gennemgået vellykket evaluering i samarbejde med patientmålgrupper.

#### Afsnit 3:

Hvis De/du har taget/brugt for meget/mange (navn):

**Det er vigtigt, at du tager den dosis der står på etiketten fra apoteket eller som aftalt med din læge. Du må ikke øge eller nedsætte din dosis uden at have fået lægelig vejledning.**

#### Afsnit 4

Hyppigheden er ikke kendt, men følgende kan også ses:

**• Søvnproblemer, depression eller følelse af bekymring, rastløshed, nervøsitet, stærk anspændthed eller irritabilitet. Disse bivirkninger er mest sandsynlige hos børn.**

## Intranasale kortikosteroider

### Pkt. 4.4 i SmPC

#### Section 4.4 (Special warnings and precautions for use)

*Systemiske bivirkninger af nasale kortikosteroider kan forekomme, specielt ved høje doser givet i længere perioder. Disse bivirkninger er langt mindre sandsynlige end ved oral steroidbehandling og kan variere mellem individuelle patienter og forskellige kortikosteroidpræparater. Eventuel systemisk virkning kan omfatte Cushings syndrom, cushingoide træk, binyrebarksuppression, væksthæmning hos børn og unge, katarakt, glaukom og sjældnere, en række psykiske og adfærdsrelaterede bivirkninger, inklusiv psykomotorisk hyperaktivitet, søvnforstyrrelser, angst, depression eller aggression (specielt hos børn).*

#### Indlægsseddel

**Bemærk:** Teksten i indlægssedler varierer meget for forskellige produkter. Teksten foreslået nedenfor er primært baseret på patient-venlige tekster taget fra indlægssedler, der har gennemgået vellykket evaluering i samarbejde med patientmålgrupper.

#### Afsnit 3:

**Hvis De/du har taget/brugt for meget/mange (navn):**

**Det er vigtigt, at du tager den dosis, der står på etiketten fra apoteket, eller som aftalt med din læge. Du bør kun tage så meget som din doktor har anbefalet; tager du mere eller mindre kan dine symptomer blive værre.**