



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Section 4.2: Posology and method of administration

Rev. 1

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SmPC training presentation

**Note:** for full information refer to the European Commission's [Guideline on summary of product characteristics \(SmPC\)](#)

SmPC Advisory Group

An agency of the European Union





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# I. General objectives of section 4.2

This section should include all the relevant information to guide the posology recommendation taking into account patient and product specificities



## II.1 Conditions for use

In case of **restricted medical prescription**, this section should be started by specifying the conditions

SmPC examples

[1 restricted prescription](#)

[2 restricted prescription](#)

In case of **specific safety need**, any recommended restriction to a particular setting should also be stated e.g.

“restricted to hospital use only” or “appropriate resuscitation equipment should be available”

[3 specific safety need](#)

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# Example 1–restricted medical prescription

In case of **restricted medical prescription**, this section should be started by specifying the conditions

Active substance XY 150 mg/300 mg film-coated tablets

Therapy should be initiated by a physician experienced in the management of HIV infection.



## Example 2–restricted medical prescription

In case of **restricted medical prescription**, this section should be started by specifying the conditions

Active substance X 6 mg solution for injection

Active substance X therapy should be initiated and supervised by physicians experienced in oncology and/or haematology.



## Example 3–specific safety need

In case of **specific safety need**, any recommended restriction to a particular setting should also be stated

Active substance X 40 micrograms per dose iontophoretic transdermal

Active substance X should be restricted to hospital use only.



## Example 4–specific safety need

In case of **specific safety need**, any recommended restriction to a particular setting should also be stated

Active substance X 30 MU/0.5 ml solution for injection or infusion in pre-filled syringe

The mobilisation and apheresis procedures should be performed in collaboration with an oncology-haematology centre with acceptable experience in this field and where the monitoring of haematopoietic progenitor cells can be correctly performed.





## II.2 Posology

**Dosage** for each indication, each method/route of administration as appropriate:

**Dose recommendations**

e.g. mg, mg/kg, mg/m<sup>2</sup>

**Frequency of dosing**

e.g. once or twice daily or every 6 hours

SmPC examples

[5 dosage](#)

[6 dosage](#)

[7 dosage](#)

Where appropriate, a reference to official recommendation should be made  
e.g. for primary vaccination and antibiotics as well as for booster dose)



## Example 5-dosage

**Dosage** should be clearly specified for each method/route of administration and for each indication.

**Dose recommendations**

**Frequency of dosing**

Active substance X 250 mg capsules

Use in renal transplant:

Adults: oral active substance X should be initiated within 72 hours following transplantation. The recommended dose in renal transplant patients is 1.0 g administered twice daily (2 g daily dose).



## Example 6-dosage

**Dosage** should be clearly specified for each method/route of administration and for each indication.

**Dose recommendations –mg/kg**

**Frequency of dosing**

Active substance X 25 mg/ml concentrate for solution for infusion

Metastatic breast cancer (mBC)

The recommended dose of active substance X is 10 mg/kg of body weight given once every 2 weeks or 15mg/kg of body weight given once every 3 weeks as an intravenous infusion.



## Example 7-dosage

**Dosage** should be clearly specified for each method/route of administration and for **each indication**.

**Dose recommendations –mg/m<sup>2</sup>**

**Frequency of dosing**

### Active substance X 2 mg/ml concentrate for solution for infusion

#### *Breast cancer/Ovarian cancer:*

Active substance X is administered intravenously at a dose of 50 mg/m<sup>2</sup> once every 4 weeks for as long as the disease does not progress and the patient continues to tolerate treatment.

#### *AIDS-related KS:*

Active substance X is administered intravenously at 20 mg/m<sup>2</sup> every two-to-three weeks. Avoid intervals shorter than 10 days as medicinal product accumulation and increased toxicity cannot be ruled out. Treatment of patients for two-to-three months is recommended to achieve a therapeutic response. Continue treatment as needed to maintain a therapeutic response.

The dose of active substance X is diluted in 250 ml 5 % (50 mg/ml) glucose solution for infusion and administered by intravenous infusion over 30 minutes.



## II.3 Other posology requirements (illustrated by SmPC examples)

**Normal duration of use.** [e.g. 8](#)

**Maximum recommended dose.**  
[e.g. 9 single](#) [10 single](#) [11 daily](#) [12 total](#)

**Dose titration.** [e.g. 13](#)

**Advice on discontinuation.** [e.g. 14](#)

Advice if **dose(s) missed.**  
[e.g. 15](#) [16 vomiting](#)

Advice relevant for **dose adjustment**  
e.g. from monitoring of clinical signs and symptoms +/- lab investigations.  
[e.g. 17](#)

**Preventative measures** for **adverse reactions.** [e.g. 18](#)

Recommendation related to **non-serious adverse reaction that are frequent but transient or manageable** with dose-titration. [e.g. 19](#)

Intake in relation to **food and drink.** [e.g. 20](#)

**Interactions** requiring dose adjustments. [e.g. 21](#)

Advice regarding **repeat use.** [e.g. 22](#)



## Example 8–normal duration of use

**Normal duration of use** and any **restrictions on duration**

Active substance X 2 mg/ml concentrate for solution for infusion

Active substance X is administered intravenously at a dose of 50 mg/m<sup>2</sup> once every 4 weeks for as long as the disease does not progress and the patient continues to tolerate treatment.



## Example 9-maximum dose-single

**Maximum recommended dose** (single)

### Active substance X 25 micrograms/ml solution for infusion

Dosing of active substance X should be initiated at 2.4 µg/day and titrated on an individual patient basis according to the patient's analgesic response and adverse reactions. Patients should be titrated in dose increments of  $\leq 2.4$  µg/day, up to a maximum dose of 21.6 µg/day. The minimal interval between dose increases is 24 hours; the recommended interval, for safety reasons, is 48 hours or more. If necessary the dose can be decreased by any amount (including stopping the infusion) for the management of adverse reactions. Approximately 75% of patients who respond satisfactorily to treatment require a dose of  $\leq 9.6$  µg/day.



## Example 10-maximum dose-single

### Maximum recommended dose (single)

Active substance X 6,000 units. Powder and solvent for solution for injection

Active substance X should be administered on the basis of body weight, with a maximum dose of 10,000 units (50 mg active substance X).





## Example 11-maximum dose-daily

### Maximum recommended dose (daily)

Active substance X 20 mg powder for solution for injection

The recommended dose is 40 mg administered intravenously (IV) or intramuscularly (IM), followed every 6 to 12 hours by 20 mg or 40 mg as required, not to exceed 80 mg/day.



## Example 12-maximum dose-total

**Maximum recommended dose** (total)

Active substance X

Squamous cell carcinoma

Intramuscular or intravenous injection of  $10\text{--}15 \times 10^3 \text{ IU/m}^2$  once or twice a week.

Treatment can be continued in the weeks following this or, which is more common, with intervals of 3-4 weeks, up to a total cumulative dose of  $400 \times 10^3 \text{ IU}$ .



# Example 13-dose titration

## Dose titration

### Active substance X 100 micrograms buccal tablets

#### Dose titration

Active substance X should be individually titrated to an “effective” dose that provides adequate analgesia and minimises undesirable effects. In clinical studies, the effective dose of active substance X for breakthrough pain was not predictable from the daily maintenance dose of opioid. Patients should be carefully monitored until an effective dose is reached.

#### Titration in patients not switching from other fentanyl containing products

The initial dose of active substance X should be 100 micrograms, titrating upwards as necessary through the range of available tablets strengths (100, 200, 400, 600, 800 micrograms).

#### Titration in patients switching from other fentanyl containing products

Due to different absorption profiles, switching must not be done at a 1:1 ratio. If switching from another oral fentanyl citrate product, independent dose titration with active substance X is required as bioavailability between products differs significantly. However, in these patients, a starting dose higher than 100 micrograms may be considered.



## Example 14-advice on discontinuation

The normal duration of use and any restrictions on duration and, **if relevant, the need for tapering off, or advice on discontinuation**

Active substance X 30 mg hard gastro-resistant capsules

### Discontinuation of treatment

Abrupt discontinuation should be avoided. When stopping treatment with active substance X the dose should be gradually reduced over a period of at least one to two weeks in order to reduce the risk of withdrawal reactions (see sections 4.4 and 4.8). If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose, but at a more gradual rate.



## Example 15-missing dose(s)

**Advice on action to be taken if one or more dose(s) is (are) missed**, or e.g. in case of vomiting (the advice should be as specific as possible, taking into consideration the recommended frequency of dosing and relevant pharmacokinetic data)

### Active substance X 100 mg tablets

The recommended dose of active substance X is 200 mg (two 100 mg tablets) taken orally twice daily(b.i.d.), following a meal (see section 5.2).

If the patient misses a dose of active substance X within 6 hours of the time it is usually taken, the patient should be told to take it following a meal as soon as possible and then take the next dose at the regularly scheduled time. If a patient misses a dose by more than 6 hours of the time it is usually taken, the patient should be told not to take the missed dose and simply resume the usual dosing schedule.



## Example 16-vomiting

Advice on action to be taken if one or more dose(s) is (are) missed, or e.g. **in case of vomiting** (the advice should be as specific as possible, taking into consideration the recommended frequency of dosing and relevant pharmacokinetic data)

Active substance X 30 mg tablet

If vomiting occurs within 3 hours of active substance X intake, another tablet should be taken.



## Example 17-dose adjustment

**Advice relevant for dosage adjustment** e.g. monitoring of clinical symptoms and signs, and/or laboratory investigations, including blood concentrations should be mentioned where appropriate with cross-reference to other sections where appropriate

Active substance X 75 mg powder and solvent for solution for injection

The appropriate dose and dosing frequency of active substance X is determined by baseline IgE (IU/ml), measured before the start of treatment, and body weight (kg). Prior to initial dosing, patients should have their IgE level determined by any commercial serum total IgE assay for their dose assignment. Based on these measurements 75-600 mg of active substance X in 1 to 4 injections may be needed for each administration.



# Example 18-adverse reactions

Advice on **preventive measures to avoid certain adverse drug reactions** (e.g. administration of antiemetics) with cross-reference to section 4.4

## Active substance X 20 mg concentrate and solvent for solution for infusion

### Section 4.2

For breast, non-small cell lung, gastric, and head and neck cancers, premedication consisting of an oral corticosteroid, such as dexamethasone 16 mg per day (e.g. 8 mg BID) for 3 days starting 1 day prior to active substance X administration, unless contraindicated, can be used (see section 4.4). Prophylactic G-CSF may be used to mitigate the risk of hematological toxicity.

### Section 4.4

For breast and non-small cell lung cancers, premedication consisting of an oral corticosteroid, such as dexamethasone 16 mg per day (e.g. 8 mg BID) for 3 days starting 1 day prior to active substance X administration, unless contraindicated, can reduce the incidence and severity of fluid retention as well as the severity of hypersensitivity reactions.





## Example 19-non-serious adverse reactions

It may also be relevant to **recommend not to prematurely discontinue a treatment in case of specific non-serious adverse reaction(s) that are frequent but transient or manageable with dose titration**

### Active substance X 1.5 mg hard capsules

The starting dose is 1.5 mg twice a day. If this dose is well tolerated after a minimum of two weeks of treatment, the dose may be increased to 3 mg twice a day. Subsequent increases to 4.5 mg and then 6 mg twice a day should also be based on good tolerability of the current dose and may be considered after a minimum of two weeks of treatment at that dose level. If adverse reactions (e.g. nausea, vomiting, abdominal pain or loss of appetite), weight decrease or worsening of extrapyramidal symptoms (e.g. tremor) in patients with dementia associated with Parkinson's disease are observed during treatment, these may respond to omitting one or more doses. If adverse reactions persist, the daily dose should be temporarily reduced to the previous well-tolerated dose or the treatment may be discontinued.



## Example 20-food intake

**Dosage** should be clearly specified for **each method/route of administration** and for **each indication**

Intake in relation to **food**

Active substance X 25 mg film-coated tablets

Non-small cell lung cancer:

The recommended daily dose of active substance X is 150 mg taken at least one hour before or two hours after the ingestion of food.



## Example 21-interactions

**Interactions requiring specific dose adjustments** with cross-reference to appropriate sections of the SmPC

Active substance X 75 mg hard capsules

*Concomitant use of active substance X with amiodarone or verapamil:*

Dosing should be reduced to 150 mg active substance X daily in patients who receive concomitantly active substance X and amiodarone or verapamil (see sections 4.4 and 4.5).

In patient with moderate renal impairment and concomitantly treated with active substance X and verapamil, a dose reduction of active substance X to 75 mg daily should be considered (see sections 4.4 and 4.5).



## Example 22-repeat use

Advice regarding repeat use, with any **information on intervals to be observed between courses of treatment**, as appropriate

Active substance X 1 mg powder for solution for injection

The recommended starting dose of active substance X is 1.3 mg/m<sup>2</sup> body surface area twice weekly for two weeks (days 1, 4, 8, and 11) followed by a 10-day rest period (days 12-21). This 3-week period is considered a treatment cycle. At least 72 hours should elapse between consecutive doses of active substance X.



## II.4 Special populations

Dosage adjustments or other posology related information in specific patient groups should be stated where necessary, in well-defined sub-sections ordered by importance

Elderly population

SmPC examples  
[23](#), [24](#) **elderly**

Renal impairment

[25](#) **renal**

Hepatic impairment

[26](#) **hepatic**

Other special populations

[27](#) **other**



## Example 23-elderly

Elderly population; it should be made **clear whether or not any dosage adjustment is necessary in any subsets of the elderly population**, with cross-reference to other sections providing information in elderly, e.g. 4.4, 4.5, 4.8 or 5.2

Active substance X 5 mg hard capsules

Older patients may be sensitive to the effects of hypnotics; therefore, 5 mg is the recommended dose of active substance X.



## Example 24-elderly

Elderly population; it should be made **clear whether or not any dosage adjustment is necessary in any subsets of the elderly population**, with cross-reference to other sections providing information in elderly, e.g. 4.4, 4.5, 4.8 or 5.2

Active substance X 1.5 mg prolonged-release tablets

Dosing recommendations for older patients with normal renal function (80 ml/min) are the same as for adults with normal renal function. However, because older patients may have diminished renal function, dose adjustments may be required according to their renal function status (see Renal impairment below).



## Example 25-renal

Renal impairment; the **dose recommendation should relate as precisely as possible to the cut-off values for biochemical markers of renal impairment** in clinical studies and to the results of these studies

Active substance X 1.5 mg/0.3 ml solution for injection, pre-filled syringe

Renal impairment – active substance X must not be used in patients with creatinine clearance  $<20$  ml/min (see section 4.3). The dose should be reduced to 1.5 mg once daily in patients with creatinine clearance in the range of 20 to 50 ml/min (see sections 4.4 and 5.2). No dosage reduction is required for patients with mild renal impairment (creatinine clearance  $>50$  ml/min).





## Example 26-hepatic

Hepatic impairment; **specified according to the patients included in studies**, for instance 'alcohol-related cirrhosis' and the **definitions used in studies**, for instance Child-Pugh score/grade of the patients

Active substance X 20 mg powder for solution for injection

Hepatic Impairment: No dosage adjustment is generally necessary in patients with mild hepatic impairment (Child-Pugh score 5-6). Introduce active substance X with caution and at half the usual recommended dose in patients with moderate hepatic impairment (Child Pugh score 7-9) and reduce the maximum daily dose to 40 mg. There is no clinical experience in patients with severe hepatic impairment (Child-Pugh score  $\geq 10$ ), therefore its use is contraindicated in these patients (see sections 4.3 and 5.2).



## Example 27-other

**Other special populations** (e.g. overweight patients)

Active substance X 45 mg solution for injection

Patients with body weight > 100 kg

For patients with a body weight > 100 kg the dose is 90 mg administered subcutaneously at week 0, followed by a 90 mg dose at week 4, then every 12 weeks thereafter (see section 5.1).

In patients weighing > 100kg, 45 mg was also shown to be efficacious. However, 90mg resulted in greater efficacy in these patients.



## II.5 Paediatric population

Information should cover all subsets of the paediatric population

### ✓ Indication in paediatric population:

Dose recommendations (e.g. mg, mg/kg, mg/m<sup>2</sup>) should be specified per dose interval for the paediatric subsets where the product is indicated

- Same posology in adults and children; statement to this effect is sufficient
- More appropriate strength(s) and/or formulation available (e.g. oral solution for infants)
- When no adequate paediatric formulation can be developed, provide details regarding extemporaneous preparations in section 6.6 and cross refer to section 4.2

SmPC examples  
[28 posology](#)

[29 same  
posology](#)

[30 more appropriate  
formulation/strength](#)

[31 extemporaneous  
preparation](#)

✗ No indication in some or all subsets: [standard statements should be used](#)



# No indication in some or all subsets

If there is no indication for the product in some or all subsets of the paediatric population, no posology recommendation can be made, but available information should be summarised using the following **standard statements (one or combination of several as appropriate)**:

## SmPC guideline

- The <safety> <and> <efficacy> of X in children aged x to y <months, years> *<or any other relevant subsets e.g. weight, pubertal age, gender>* <has><have> not <yet> been established.  
One of the following statements should be added:
  - <No data are available>.
  - or
  - <Currently available data are described in section <4.8><5.1><5.2> but no recommendation on a posology can be made >
- X should not be used in children aged x to y <years, months> *<or any other relevant subsets e.g. weight, pubertal age, gender>* because of <safety> <efficacy> concern(s) *<concern(s) to be stated with cross reference to sections detailing data (e.g. 4.8 or 5.1) >*.
- There is no relevant use of X in <the paediatric population> <in children aged x to y> <years, months> > *<or any other relevant subsets e.g. weight, pubertal age, gender>* in the indication(s) <specify indication(s)>.
- X is contraindicated in children aged x to y <years, months> *<or any other relevant subsets e.g. weight, pubertal age, gender>* <in the indication ...> (cross-reference to section 4.3).



# Example 28-paediatric population-posology

## **Posology recommendations for each subset**

The following should be given

- Dose expressed according to weight or body surface area
- Dose specified per dose interval

## Active substance X 2.5 mg oromucosal solution

Paediatric population

Standard doses are indicated below:

Infants, toddlers, children and adolescents:

Age range	Dose	Label colour
3 to 6 months hospital setting	2.5mg	Yellow
> 6 months to < 1 year	2.5mg	Yellow
1 year to < 5 years	5 mg	Blue
5 years to < 10 years	7.5 mg	Purple
10 years to < 18 years	10 mg	Orange

Carers should only administer a single dose of active substance X. If the seizure has not stopped within 10 minutes after administration of active substance X, emergency medical assistance must be sought and the empty syringe given to the healthcare professional to provide information on the dose received by the patient.



## Example 29-paediatric population-same posology

Posology same in adults and children; statement to this effect is sufficient

Active substance X 0.5 mg/ml, Eye Drops, solution in multidose container

Paediatric population

Active substance X may be used in paediatric patients (3 years of age and older) at the same posology as in adults.



## Example 30-appropriate strengths/formulation

Mention if there are **more appropriate strength(s) and/or formulation available** (e.g. oral solution for infants) in **Section 4.2 of the SmPC of the less appropriate presentation**

Active substance X 30 mg hard capsule

Adults, adolescents or children (> 40 kg) who are unable to swallow capsules may receive appropriate doses of active substance X suspension.



## Example 31-extemporaneous preparation

No adequate paediatric formulation can be developed, detailed instructions to obtain extemporaneous preparation in section 6.6 with cross-reference in section 4.2

### Active substance X 20 mg film-coated tablets

#### Paediatric population (1 year to 17 years)

For paediatric patients aged 1 year to 17 years old, the recommended dose in patients  $\leq 20$  kg is 10 mg (1 ml of compounded suspension) three times a day and for patients  $> 20$  kg is 20 mg (2 ml of compounded suspension or 1 tablet) three times a day.

For instructions on compounding of the medicinal product before administration, (see section 6.6).





## II.6 Method of administration

Any special precautions in manipulation or administration of the product by healthcare professionals, the patient or care should be mentioned (with a cross-reference to section 6.6 or 12)

SmPC examples

[1 precaution](#)

[2 precaution](#)

- **Route of administration and concise relevant instruction for correct administration and use**
  - Explanation for any **specific recommendation** related to use **of pharmaceutical form**
  - Information on **alternative method(s) to facilitate administration** particularly for administration **via feeding tubes** (when supportive data available)
  - For parenteral formulations, information **on rate or speed of injection or infusion** should be provided.
- A **Cross-reference to 6.6** (Instructions for preparation or reconstitution should be provided in section 6.6)

[3 instruction for correct admin + use](#)

[4 specific recommendation-pharm form](#)

[5 specific recommendation - pharm form](#)

[6 alternative method - feeding tube](#)

[7 rate or speed of infusion](#)

[8 cross-reference to 6.6](#)



# Example 1-precaution before administration

Any special precautions in manipulation or administration of the product by healthcare professionals

Active substance X 500 mg tablets

Section 4.2 - Method of administration

Patients should be advised not to use any tablets showing signs of deterioration, and caregivers to wear disposable gloves when handling the tablets.



## Example 2-precaution before administration

Any special precautions in manipulation or administration of the product

### Active substance X 0.44 mg/ml solution for injection

#### **Section 4.2 - Method of administration**

The dose may be diluted in up to 100 ml of sodium chloride 9 mg/ml (0.9%) solution for injection. It should not be diluted in glucose 5% infusion solution. For instructions on the dilution of the medicinal product before administration, see section 6.6. Good peripheral venous access, or a patent central line, should be ensured prior to administration. In the event of extravasation, treatment should be symptomatic. For information relevant to the handling of cytotoxic drugs see section 6.6.

#### **Section 6.6 – Special precautions for disposal and handling of the product**

Active substance X is a cytotoxic anticancer medicinal product and, as with other toxic compounds, caution should be exercised in its handling. The use of gloves, goggles, and protective clothing is recommended. If the skin comes into contact with the solution it should be washed immediately and thoroughly with soap and water. If it contacts mucous membranes, the membranes should be flushed thoroughly with water. Active substance X should only be prepared and administered by personnel appropriately trained in handling of cytotoxic agents. Pregnant staff should not handle active substance X .

Using aseptic technique active substance X can be diluted up to 100 ml with sodium chloride 9 mg/ml (0.9%) solution for injection. It must not be mixed with other medicinal products and should not be diluted in glucose 5% infusion solution.



## Example 3-concise relevant instruction for admin + use

The following should be given

- **Route of administration**
- **Concise relevant instruction for correct administration and use**

**Explanation** should be given for any **specific recommendation related to use of pharmaceutical form**

Active substance X 150 mg film-coated tablets

### **Method of Administration**

For oral use.

Tablets should be swallowed whole with a glass of plain water (180 to 240ml) while the patient is sitting or standing in an upright position. Patients should not lie down for 1 hour after taking active substance X.

Plain water is the only drink that should be taken with active substance X. Please note that some mineral waters may have a higher concentration of calcium and therefore, should not be used. Patients should not chew or suck the tablet, because of a potential for oropharyngeal ulceration.



## Example 4-specific recommendation pharmaceutical form

**Explanation** should be given for any **specific recommendation related to use of pharmaceutical form**

### SmPC guideline

“the coated tablet should not be chewed because of <bad taste>”  
“the enteric-coated tablet should not be crushed because coating prevents <pH sensitive degradation> <irritant effects> on the gut”  
“the coated tablet should not be broken because the coating is intended to ensure a prolonged release (see 5.2)”.



## Example 5-specific recommendation pharmaceutical form

**Explanation** should be given for any **specific recommendation related to use of pharmaceutical form**

Active substance XY 1000 mg/20 mg modified-release tablets

### Method of administration

The tablets should be taken whole, with food, in the evening or at bedtime.

To preserve the modified release properties, the tablets must not be split, broken, crushed, or chewed before swallowing.



## Example 6-alternative method feeding tubes

The following should be given

- **Route of administration**
- **Concise relevant instruction for correct administration and use**

Information on **alternative method(s) to facilitate administration particularly for administration via feeding tubes** (when supportive data available)

Active substance X 250 mg film-coated tablets

### Method of administration

The tablet may be taken with or without food, at about the same time each day. The tablet can be swallowed whole with some water or if dosing of whole tablets is not possible, tablets may be administered as a dispersion in water (non-carbonated). No other liquids should be used. Without crushing it, the tablet should be dropped in half a glass of drinking water. The glass should be swirled occasionally, until the tablet is dispersed (this may take up to 20 minutes). The dispersion should be drunk immediately after dispersion is complete (i.e. within 60 minutes). The glass should be rinsed with half a glass of water, which should also be drunk. The dispersion can also be administered through a naso-gastric or gastrostomy tube.



## Example 7-rate or speed of infusion

For parenteral formulations, information on rate or speed of injection or infusion should be provided

Active substance X 500 mg powder for solution for infusion

Method for administration

Active substance X is to be reconstituted and then further diluted (see section 6.6) prior to administration by intravenous infusion over a period of one or four hours.





## Example 8-cross-reference to 6.6

- Route of administration
- Concise relevant instruction for correct administration and use
- Cross-reference to 6.6 (*In section 6.6, information on instructions for preparation or reconstitution should be given*)

### Active substance X 5 micrograms/0.5 ml

#### **Method of administration**

This vaccine should be administered intramuscularly.

The anterolateral thigh is the preferred site for injection in neonates and infants. The deltoid muscle is the preferred site for injection in children and adolescents.

Do not inject intravascularly.

Exceptionally, the vaccine may be administered subcutaneously in patients with thrombocytopenia or bleeding disorders.

See section 6.6 for the instructions for preparation



### III. FAQs

1. Can there be a posology recommendation if there is no indication in the population?
2. How should posology recommendations be given in a subpopulation?
3. When and how would it be relevant to refer different strengths or pharmaceutical forms in the SmPC?
4. How should restricted medical prescription be stated in the SmPC?\*



# 1. Can there be a posology recommendation if there is no indication in the population?

- A medicinal product should only be indicated in a population if a posology recommendation can be given. Therefore, if the benefit/risk assessment does not grant an indication, no posology recommendation can be given.



## 2. How should posology recommendations be given in a subpopulation?

- In addition to the recommendation in this presentation, please refer to the additional presentations on Paediatrics, Geriatric, Pharmacogenomic, the guidelines "[Evaluation of the pharmacokinetics of medicinal products in patients with impaired hepatic function](#) " and "[Evaluation of the pharmacokinetics of medicinal products in patients with impaired renal function](#)"



### 3. When and how would it be relevant to refer to different strengths or pharmaceutical forms in the SmPC?

- The SmPC should be tailored to each pharmaceutical form and strength. Reference to different strengths or pharmaceutical forms may be included in section 4.2 if the dosage regimen is based on the use of several strengths or pharmaceutical forms. A statement that a more appropriate dose/pharmaceutical form is available should be included, when applicable considering that:
  - The use of suitable pharmaceutical forms for different subpopulations should be promoted, especially in children;
  - The consistency of the indication should be ensured between the corresponding strengths/pharmaceutical forms of the reference product and generic/biosimilar ([QRD general principles regarding the SmPC information for a generic/hybrid/biosimilar product](#))

Examples of possible statement:

- *This product is also available as <tablet/oral solution>.*
- *Oral liquid formulations of <INN> may also be available.*
- *Formulation X is only suitable for <specific age group> because <...>.*
- *Other pharmaceutical forms are available for administration to patients <specific age group> who <are not able to swallow tablets> <need more precise dosing>.*



## 4. How should restricted medical prescription be stated in the SmPC?\*

- In case of restricted prescription, the SmPC will include in the beginning of section 4.2 an explanation on how the medicinal product should be supplied to patients (e.g. to be administered in a hospital setting or prescribed by specialists only, or specific type of care during the treatment of a chronic disease). For further details, see topic 3.1.11 of the [Pre-authorisation Guidance Q&As](#).



# Thank you for consulting this training presentation

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SmPC Advisory Group

Please note the presentation includes examples that may have been modified to best illustrate the related principle