



Working Group on Quality Review of Documents

Addressing the paediatric or incapacitated patient In the package leaflet

The template for the package leaflet suggests the use of a direct form of addressing the user/patient through the use of the pronoun “You”. This wording has however given rise to problems when the patient is by the nature of his/her age or illness, incapable of reading or acting on the package leaflet. In certain languages “You” can be used in a formal or informal style, depending on who is meant to be reading the Package Leaflet. In order to avoid inappropriate wording it is important to define clearly who it is aimed at and adopt the correct style accordingly.

The following is a suggestion on how to address situations in which the paediatric or incapacitated patient is in the care of a parent or a carer who is not a health professional. The administration of the medicinal product itself might, in certain cases, be done by a healthcare professional (e.g. in the case of a vaccine) but a non-professional is in charge of the overall supervision of the patient and his/her health.

Separate suggestions will be assembled for the case in which the patient is well able to read the package leaflet, but the treatment is administered by health professionals in an hospital setting.

1. If the patient is able to read, but is not able to administer the medicinal product: address the patient directly. If someone else is responsible for the preparation and administration, the parent or caretaker will vicariously take over the reading.

Example :

Tell your caregiver that you are taking Product A.

What if I miss a dose?

If you find you have forgotten to take your dose of Product A, wait and take the next dose at the usual time.

2. If the patient is completely unable to read and/or understand the package leaflet because of age or condition: address the parent or caretaker.

Example 2 (use in children)

What are the possible side effects?

As with other vaccines your child may feel pain or discomfort at the injection site, or you may see some redness and swelling at this site. However, these reactions usually clear up within a few days.

Other reactions which can occur are unusual crying, fever, drowsiness, irritability, feeding problems and gastrointestinal symptoms such as vomiting, diarrhoea.

N.B. differences in style with similar text for adult product:

Example 3 (use in adults):

What are the possible side effects?

As with other vaccines, you may feel pain or discomfort at the injection site, or you may see some redness and swelling at this site. However, these reactions usually clear up within a few days.

Other reactions which may appear include fever, headache, nausea (feeling sick), malaise (feeling unwell), tiredness and vomiting.

3. *If the product is both for adult and paediatric use, but the preparation and administration will most likely be the responsibility of an adult: address patients and/or caretaker or parent differentiating text where relevant Using the impersonal form in these cases can be helpful to avoid confusion.*

Example of unclear address	Example of clear address
<p><u>Example 4:</u></p> <p><u>HOW DO I TAKE Product B? (Posology and Method of Administration)</u></p> <p>Always take Product B exactly the way your doctor has told you. It is taken by mouth usually two times every day. Your full dose will be 7.5 ml in the morning and 7.5 ml 12 hours later. If you are a child or you are giving Product B to a child, you will start with a dose smaller than this and continue up to the maximum allowed for your size.</p> <p><u>HOW DO I MEASURE THE CORRECT DOSE OF THE SOLUTION?</u></p> <p>Open the child-proof cap by pushing down on it with your palm and twisting it counterclockwise, or in the direction of the arrow. Talk to your pharmacist if you have difficulty opening the bottle.</p> <p>To measure out the dose for children may require an oral syringe. Obtain a syringe from your pharmacist. Ask your pharmacist for instructions on how to use the syringe correctly.</p>	<p><u>Example 6:</u></p> <p>• Dosage and instructions for proper use</p> <p>Always take Product D exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.</p> <ul style="list-style-type: none">- Swallow Product D capsules whole with water or another drink. They can be taken with or without food.- <i>Adults:</i> The usual dose of Product D for adults and adolescents from 13 years of age is 1200 mg twice a day.- <i>Children:</i> The dose for children from 4 to 12 years of age will be calculated by your doctor, and depends on the child's weight. The usual dose for Product D capsules is 20 mg for each kg of body weight twice a day. The maximum daily dosage in children should not exceed 2400 mg. <p>An oral solution of Product D is available for children and adults unable to swallow capsules.</p>
<p><u>Example 5:</u></p> <p>The dose of Product C prescribed for you or your child will be calculated by your doctor according to your or your child's protein tolerance, diet and bodyweight or body surface.</p>	