

Adapalene/Benzoyl peroxide Orifarm - sammendrag av bytte

Preparat (generisk og referanse)	Generika: Adapalene/Benzoyl peroxide Orifarm, gel, 1 mg/g/25 mg/g. Referanse: Epiduo, Galderma, gel, 1 mg/g/25 mg/g.	
ATC-kode	D10AD53	
Søkegrunnlag generisk	Hybrid søknad (Artikkel 10(3) i Direktiv No 2001/83/EC)	
Bioekvivalensstudier, hentet fra Assessment report	<p>Ingen BE-studier:</p> <p>Adapalene/Benzoyl peroxide Orifarm is a product for topical application and for locally applied products, pharmacokinetic bioequivalence studies are generally not a suitable way to show therapeutic equivalence, since plasma levels are not relevant for local efficacy, although they may play a role with regard to safety. For this product conventional pharmacokinetic bioequivalence studies are not relevant due to low systemic exposure to adapalene and benzoyl peroxide. The absence of pharmacokinetic studies is acceptable.</p> <p>The applicant applies for the following indication: Cutaneous treatment of Acne vulgaris when comedones, papules and pustules are present (see section 5.1). Adapalene/Benzoyl peroxide Orifarm is indicated in adults, adolescents and children aged 9 years and over.</p> <p>Therapeutic equivalence has been demonstrated between the test product and the reference product Epiduo®, and superiority versus placebo was shown. No new adverse events were observed except for those previously known with the reference product Epiduo® 0.1%/2.5%.</p> <p>The SmPC texts proposed for Adapalene/Benzoyl peroxide Orifarm is identical to that of the reference product and is accepted.</p>	
Indikasjon / pasientgruppe	<p>Kutan behandling av Acne vulgaris ved tilstedeværelse av komedoner, papler og pustler. Adapalene/Benzoyl peroxide Orifarm er beregnet til voksne, ungdom og barn fra 9 år og oppover.</p> <p>Farmakoterapeutisk gruppe: Midler til topikal behandling av akne, D10AD Retinoider til lokal behandling av akne.</p>	
Kvalitativ sammensetning	<p><u>Adapalene/Benzoyl peroxide Orifarm:</u></p> <p>Dinatriumedetat Dokusatnatrium Glyserol (E 422) Poloksamer Propylenglykol (E 1520) Akrylamid Natriumakryloyldimetyltaurat</p>	<p><u>Epiduo:</u></p> <p>Dinatriumedetat Dokusatnatrium Glycerol Poloksamer Propylenglykol (E1520) Simulgel 600 PHA (kopolymer av akrylamid og natriumakryloyldimetyltaurat, isoheksadekan,</p>

	Isoheksadekan Polysorbat 80 (E 433) Sorbitanoleat Renset vann	polysorbat 80, sorbitanoleat) Renset vann
Vurdering i Assessment Report	The product information is acceptable. The benefit/risk is considered positive, and the application is therefore recommended for approval.	
Opptak på byttelisten i henhold til retningslinjene	Første generika. Hybrid søknad. Byttegruppens vurdering er at disse er byttbare. Sendes på høring.	