

APR has submitted for registration the Diclofenac K 5% Oral Drops File in The Netherlands

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APR has recently filed for registration of its product in Oral Drops containing as active ingredient Diclofenac Potassium at 5% concentration. The EU Standard Registration Dossier has been submitted in The Netherlands as Abridged Application vs. Cataflam 50 mg tablets. The Registration Dossier has been successfully audited by the Dutch Authorities during a Pre-registration meeting held last March 2001. Registration Approval in The Netherlands is expected during the 1st Quarter of 2002; once the product is approved in The Netherlands, APR will immediately start a Mutual Recognition Procedure using The Netherlands as Reference Member State in order to extend the Dutch Approval in all the other EU Countries.

The Product, which is going to be the first immediate release diclofenac product in Oral Drops available on the market, has been developed using the APR proprietary and patented Drug Delivery Technology. This is the 3rd APR diclofenac formulation developed so far: APR has already developed and registered a 50 mg Diclofenac Potassium in Sachet for drinkable solution and it has under registration in Switzerland the 25 and 50 mg immediate release tablets. The 50 mg Sachet has been already licensed out for Italy to Novartis Pharma where the product is currently marketed under the Brand Name "Voltfast" and recording sales of about 70'000 Units per Month. The 25 and 50 mg Tablet Form has been licensed out exclusively for Switzerland to an undisclosed Swiss Company: registration approval is expected during the 4th Quarter 2001 and the launch in Switzerland is expected during the 1st Quarter 2002; the product has been also licensed out in New Zealand and Italy. For the EU markets, APR will start a Mutual Recognition Procedure during the 1st Quarter 2002.

The Oral Drop Formulation has been already exclusively licensed out for Germany to an undisclosed German Multinational Company and non exclusively for Italy to an undisclosed local Company. APR is actively looking for Partners/Licensees interested to market the Product in the still available countries.

The Product has the following advantages: - new formulation on the market; - immediate release profile; - consumer friendly formulation.