

This Alert

International Nonproprietary
Name **P.1/2**

LIFE SCIENCES

GENERIC MEDICINAL PRODUCTS

INTERNATIONAL NONPROPRIETARY NAME

List of all applications for Marketing Authorizations of generics medicinal products irrespectively of the procedures since January 30 through February 3, 2017.

▶ Diclofenac

Date of Publication: 03-02-2017

ID: 614902

Applicant: Pharmakern Portugal - Produtos Farmacêuticos, Sociedade Unipessoal, Lda.

Date of Application: 18-01-2017

Active Substance: Diclofenac diethylammonium

Dosage: 23.2 mg/g

Pharmaceutical Form: Gel

Reference Medicinal Product: Voltaren Emulgelex

Dosage of the Reference Medicinal Product: 23.2 mg/g

Pharmaceutical Form of the Reference Medicinal Product: Gel

▶ Olmesartan Medoxomil/Hydrochlorothiazide

Date of Publication: 02-02-2017

ID: 601071

Applicant: Biogaran

Date of Application: 04-09-2015

Active Substance: Olmesartan Medoxomil / Hydrochlorothiazide

Dosage: 20 mg + 12.5 mg

Pharmaceutical Form: Film-coated tablet

Reference Medicinal Product: Olmetec Plus

Dosage of the Reference Medicinal Product: 20 mg + 12.5 mg

Pharmaceutical Form of the Reference Medicinal Product: Film-coated tablet

▶ Olmesartan Medoxomil/Hydrochlorothiazide

Date of Publication: 02-02-2017

ID: 601073

Applicant: Biogaran

Date of Application: 04-09-2015

Active Substance: Olmesartan Medoxomil / Hydrochlorothiazide

Dosage: 40 mg + 12.5 mg

Pharmaceutical Form: Film-coated tablet

Reference Medicinal Product: Olmetec Plus

Dosage of the Reference Medicinal Product: 40 mg + 12.5 mg

Pharmaceutical Form of the Reference Medicinal Product: Film-coated tablet

▶ Olmesartan Medoxomil/Hydrochlorothiazide

Date of Publication: 02-02-2017

ID: 601074

Applicant: Biogaran

Date of Application: 04-09-2015

Active Substance: Olmesartan Medoxomil / Hydrochlorothiazide

Dosage: 40 mg + 25 mg

Pharmaceutical Form: Film-coated tablet

Reference Medicinal Product: Olmetec Plus

Dosage of the Reference Medicinal Product: 40 mg + 25 mg

Pharmaceutical Form of the Reference Medicinal Product: Film-coated tablet

▶ Dexametopreno

Date of Publication: 01-02-2017

ID: 614863

Applicant: KRKA d.d., Novo mesto

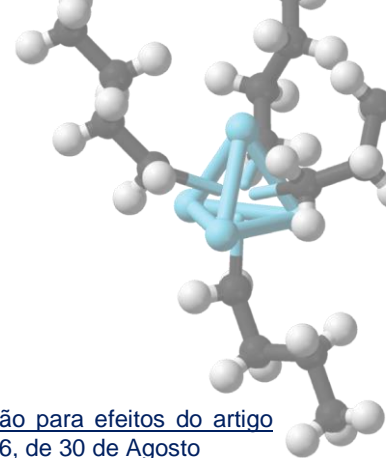
Date of Application: 11-01-2017

Active Substance: Dexametopreno trometamol

Dosage: 50 mg/2 ml

Pharmaceutical Form: Solution for Injection

Reference Medicinal Product: Kettese



Dosage of the Reference Medicinal Product: 50 mg/2 ml
Pharmaceutical Form of the Reference Medicinal Product: Solution for Injection

Source: Infarmed

For more information: [Publicação para efeitos do artigo 15º-A do Decreto -Lei n.º 176/2006, de 30 de Agosto](#)

▶ **Moxifloxacin**

Date of Publication: 31-01-2017
ID: 611168
Applicant: Bluepharma - Indústria Farmacêutica, S.A.
Date of Application: 22-08-2016
Active Substance: Moxifloxacin hydrochloride
Dosage: 40 mg
Pharmaceutical Form: Film-coated tablet
Reference Medicinal Product: Avelox
Dosage of the Reference Medicinal Product: 40 mg
Pharmaceutical Form of the Reference Medicinal Product: Film-coated tablet

▶ **Nortriptyline**

Date of Publication: 31-01-2017
ID: 614762
Applicant: Tecnifar - Indústria Técnica Farmacêutica, S.A.
Date of Application: 06-01-2017
Active Substance: Nortriptyline
Dosage: 25 mg
Pharmaceutical Form: Coated tablet
Reference Medicinal Product: Nortrol
Dosage of the Reference Medicinal Product: 25 mg
Pharmaceutical Form of the Reference Medicinal Product: Coated tablet

