



Synapse Platform User Guide

Prescription analysis modules



Side Effects module

LABELS AND SYMBOLS

 Important safety or operating instructions

 See the instruction manual

 Medical device in accordance with Directive 93/42/EEC

EXPECTED USE

The “**Side Effects**” module promotes the proper use of medication by searching for and displaying side effects.

This module is intended for healthcare professionals who manage patients' medications (doctors, pharmacists, nurses, midwives, dentists, etc.).

It informs the user of how frequently side effects occur (very common, common, uncommon, rare, very rare or not known). It informs the user of all the potential side effects and their frequencies related to a prescription with several medications.

To do this, there are two ways to look for a side effect:

- 1. A search bar with an autocomplete feature using MedDRA terms**
- 2. The list of effects identified in the prescription entered, classified by frequency or by medication.**

The data come from the French National Agency for Medicines' public drug database, and apply to medications available in France but, by extrapolation, also in Europe.

PREREQUISITES BEFORE USE

No training is required before using this module.

The data sheet describes the minimum requirements necessary to operate this module as intended.

Side Effects module

HOW TO USE

The module has two functions:

“Search for a side effect”

Search for a side effect

This feature lets you search for whether a given side effect may be caused by one or more of the medications in the prescription entered.

Enter the desired side effect in the autocomplete search bar (*MedDRA coding*) and select it from the list.

If the side effect is known and reported for one or more medications, the degree of frequency (very common, common, etc.) of how often the side effect occurs appears for each medication concerned.

To perform a new search, click on the **“Return to list of effects”** button located below the current search results.

“All side effects”

Search for a side effect



orthostatic hypotension

symptomatic orthostatic hypotension

aggravated orthostatic hypotension

Orthostatic hypotension

Drug

Frequency

furosemide

● Very Common

bisoprolol fumarate

● Uncommon

Frequency of side effect



Go back to the list of effects

Side Effects module

HOW TO USE

All side effects

This feature shows you all the side effects of the medications in the prescription.

The results can be filtered in two ways:

- 1 By frequency:** the combined side effects for all medications are displayed by degree of frequency
- 2 By medication:** side effects are classified by medication, and by degree of frequency for each medication

Undesirable effects

Note: the results you obtain depend on the information you enter (medicines and patient profile)

1 By occurrence frequency

By drug **2**

Very common

Bradycardia Dehydration Hypovolaemia Orthostatic hypotension Triglyceride analyses

Common

Asthenia Constipation Diarrhoea Elevated cholesterol Fatigue Feeling cold Gastrointestinal disorders Gout Haemoconcentration Headache
Heart failures Hepatic encephalopathy Hypokalaemia Hyponatraemia Hypotension Nausea Vertigo Vomiting

3 See the less frequent effects 

By default, it only displays very common and common side effects. Click on “**Show less common effects**” **3** to get a list with the rest of the side effects.

Side Effects module

WARNINGS

The results provided depend directly on **the data entered beforehand** (list of medications). Make sure the information you enter is accurate to get reliable results.

 In case of uncertainty about an adverse effect information, please consult the RCP

INFORMATION IN THE EVENT OF ANY ISSUES

Please notify us of any complaint or malfunction related to the device at contact@synapse-medicine.com

ADMINISTRATIVE INFORMATION



Manufacturer:

Synapse Medicine

3 rue Lafayette 33 000 Bordeaux

Class I medical device



Instructions Side Effects Module - PRO - version v1 (September 2021)