

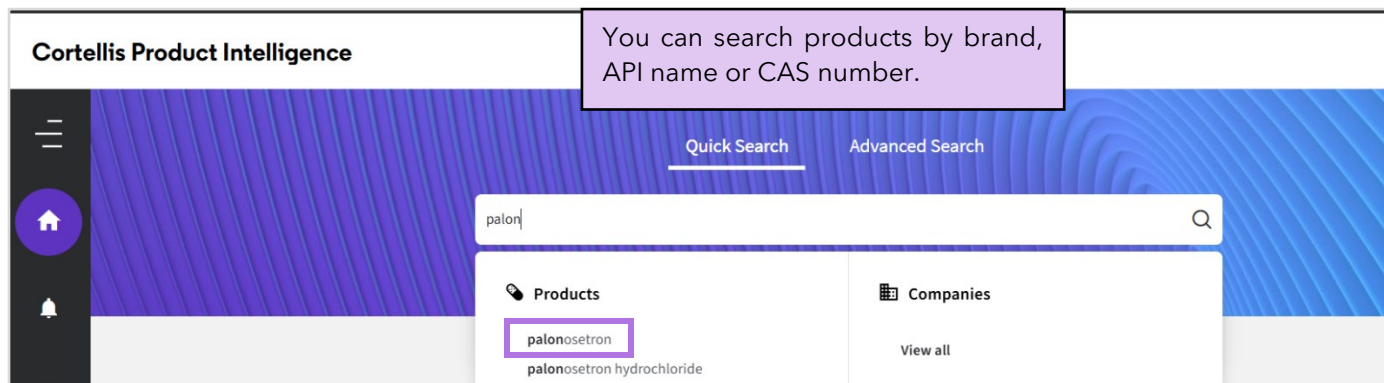
# Find links between API and finished dose manufacturers with the US and EU Labels Information table

This guide explains how to identify API and Finished dose manufacturers as well as other companies associated with a product in a few simple steps. The US and EU Labels Information table is available in the 'Launches & Pack Prices' tab\* in product records and provided by NIH Dailymed, ANSM and other sources with monthly updates.

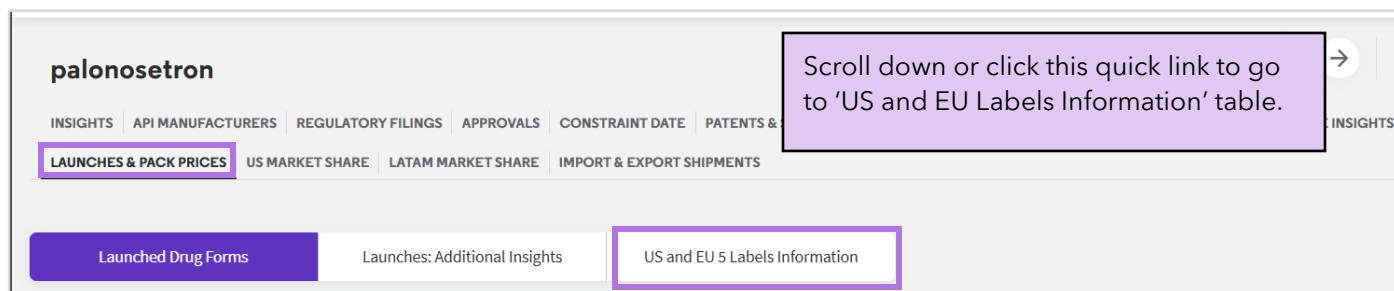
This table helps identify alliances and potential business partners you could work with and provides a more detailed picture of the supply chain and potential risks that can affect it, e.g. if a manufacturer is a single source of API working with several Finished dose companies or if a Finished dose company is already working with several API sources.

**Example:** Identify Finished dose manufacturers and other companies associated to palonosetron. Are companies manufacturing their own API? Who are they working with? Who are they selling to?

1. Login to [Cortellis Product Intelligence](#) and search palonosetron.



2. Go to 'Launches & Pack Prices' tab and scroll down to 'US and EU Labels Information' table.



- Identify API and finished dose manufacturers as well as pack details in this table. This data helps you answer questions such as: Are they manufacturing the API themselves? Who is manufacturing their finished product (dose form, strength)? Where are competitors sourcing their API from?

US and EU 5 Labels Information

Filters Customize Columns Export

Manufacturer column refers to Finished Dose Manufacturer.

ACTIVE INGREDIENT	COUNTRY/TERRITORY	STRENGTH	API SOURCE	MANUFACTURER	REPACKAGER	LABELER
palonosetron	France	250 ug	None reported	Laboratorio Reig Jofre, S.A. Reig Jofre Laboratory, SA	None reported	None reported
palonosetron hydrochloride	USA	0.075 mg per 1.5 mL	HAS Healthcare Advanced Synthesis	Curia New Mexico LLC Pierre Fabre Medicamen...	Helsinn Birex Pharmaceuticals Ltd Helsinn Birex Therapeutics Ltd	Eisai Inc.
palonosetron hydrochloride	USA	0.25 mg per 5 mL	HAS Healthcare Advanced Synthesis	Curia New Mexico LLC Pierre Fabre Medicamen...	Helsinn Birex Pharmaceuticals Ltd Helsinn Birex Therapeutics Ltd	Eisai Inc.

18 filters are available at the top left to focus on a given country, company and include/exclude discontinued labels among other options.

Apply Filters Reset all filters

Agency

Analysis

API Source

Application Holder

Application

Country/Territory

**Discontinued Labels**

Distributor

Excipients

Granted Date

Labeler

Label Revision Date

Manufacturer

Discontinued Labels

Discontinued Labels records can be hidden from the table view with the 'Discontinued Labels' toggle is displayed under the filter name

Discontinued Labels ☒

Cancel Apply

Use 'Discontinued labels' filter to exclude packs that are no longer in the market.

4. Scroll to the right to find distributors, repackagers and other companies involved and read other details, when available.

US and EU 5 Labels Information

Filters Customize Columns Export

Excipients (28) Clear all filters

Excipients information can also be found in this table.

ACTIVE INGREDIENT	COUNTRY/TERRITORY	APPLICATION HOLDER	NDC CODE	LABEL REVISION DATE	MARKETING STATUS	EXCIPIENTS	AGENCY
palonosetron	France	LABORATORIO REIG JOF... Laboratorio Reig Jofre Sa	None reported	None reported	VALID	The active substance is palonosetron each ml of solution contains 50 ***	ANSM
palonosetron	France	KALCEKS AS Kalceks As	None reported	None reported	VALID	The active substance is: palonosetron (in hydrochloride form), 50 ml ***	ANSM
palonosetron hydrochloride	USA	High Labs Sandoz AG	0781-3312 L2	05-Feb-2024	ANDA	hydrochloric acid   edetate disodium   water   sodium hydroxide   ci ***	DailyMed
palonosetron hydrochloride	USA	icines Inc Teva Pharmaceutical In...	0703-4094 L2	24-Jan-2020	ANDA	water   trisodi dihydrate   so hydrochlori Excipients hydrochloric acid   edetate disodium   water   sodium hydroxide   citric acid monohydrate   trisodium citrate dihydrate   mannitol	

5. Click 'Customize columns' to hide, show and reorder columns in your table.

Customize Columns Export

Click 'Export' to download table to MS Excel.

Hide All / Show All

- Active Ingredient
- Country/Territory
- Pack Description
- Granted Date
- Distributor
- Trade Name
- Dose Form
- Strength
- API Source
- Manufacturer

As of May 2025: The main API source of palonosetron in the US was HAS Healthcare Adv Synthesis whereas finished dose forms were produced mostly by Qilu Pharma and Baxter Oncology. In addition, Gland Pharma was manufacturing their own API and finished product in the US.

Finished dose manufacturers in France include Reig Jofre Laboratory and AS Kalceks.

\* Launches & Pack Prices tab is only available to users with access to Cortellis Product Global and Premium.

To find out what's included in your subscription, contact your Clarivate account manager or [lsh.support@clarivate.com](mailto:lsh.support@clarivate.com).