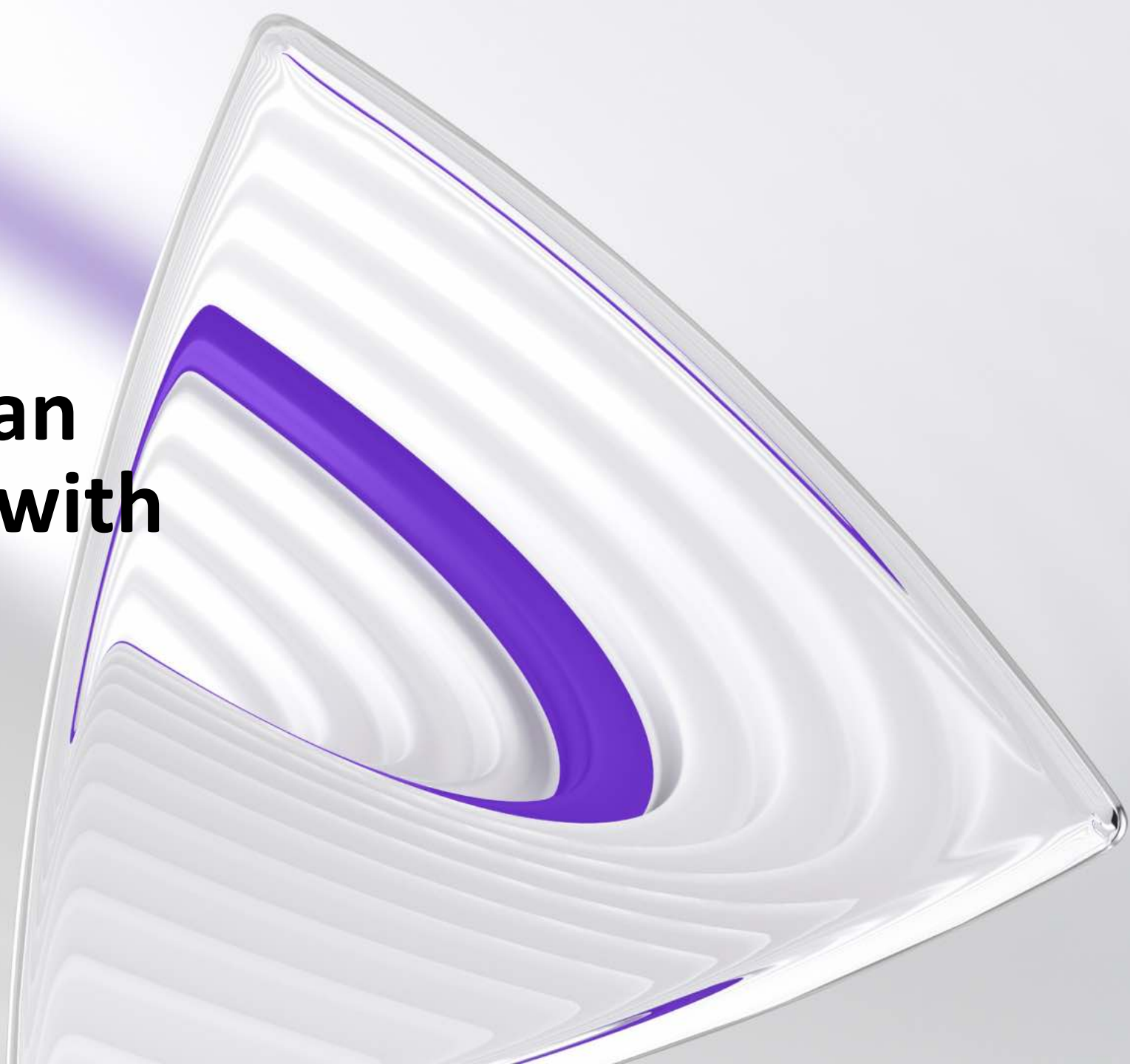




**Anticipate and plan
generic launches with
Cortellis Generics
Intelligence**



Plan and anticipate generic launches with Cortellis Generics Intelligence

Questions you need to answer:

- When can I expect a product to lose exclusivity?
- Has anyone else already filed US patent challenges?

Common challenges:

- Relying on partial data to determine when a drug will go generic.
- Evaluating new products or competitor drugs based on incomplete data.
- Loss of revenue due to inaccurate data and poor product selection.

3 steps

Find your answers with
Cortellis Generic Intelligence

1. Identify date(s) when a product will “go generic” in different markets, eg: Belgium, Italy and the USA.
2. Understand which exclusivities are currently preventing generic launches.
3. Find patent challenges already filed in the USA.

1. Identify the date when a product will “go generic”

Once in the product record, go to **Constraint Date Forecast & Exclusivities** tab to find the Constraint Date Forecast* and rationale.

tafamidis meglumine Alert

PRODUCT KEY INSIGHTS | API MANUFACTURERS | REGULATORY FILINGS | APPROVALS | **CONSTRAINT DATE FORECAST & EXCLUSIVITIES** | PATENTS & SPCS | US PATENT CHALLENGES | DEALS | COMPETITIVE INSIGHTS | R&D | SCIENTIFIC

LAUNCHES & PACK PRICES | US MARKET SHARE | LATAM MARKET SHARE

Filters: Country/Territory

Constraint Date Forecast & Exclusivities Customize Columns Export Showing 1-10 of 36

COUNTRY/TERRITORY ↓	CONSTRAINT DATE ↑	CONSTRAINT DATE RATIONALE	EXCLUSIVITIES
USA	03-May-2026	It is based on the expiry date of the Orphan Drug Exclusivity	New Chemical Entity exclusivity expires on 03-May-2024. tafamidis meglumine has unexpired 1 NEW CHEMICAL ENTITY (03-May-2024) and 1 ORPHAN DRUG EXCLUSIVITY (03-May-2026) exclusivities in the Orange Book.

*The Constraint Date Forecast is a proprietary algorithm to predict when a product is expected to lose exclusivity in over 30 global markets. This date is calculated considering patents, market exclusivities and data exclusivities for a specific product in a specific country. Please note that the Constraint Date Forecast should be used as a guideline and not be taken as a definitive date.

2. Understand which exclusivities are currently preventing generic launches

Select countries of interest from filters at the top to display exclusivities and their expiry dates.

The screenshot shows a web application interface with a filter menu on the left and a data table on the right. The filter menu is titled 'Country/Territory (3)' and lists several countries with checkboxes. 'Belgium' is selected and highlighted with a blue box. The data table has three columns: 'COUNTRY/TERRITORY', 'CONSTRAINT DATE', and 'CONSTRAINT DATE RATIONALE'. The 'EXCLUSIVITIES' column is highlighted with a blue box. The table shows three rows of data, with the first row (Belgium) highlighted.

COUNTRY/TERRITORY	CONSTRAINT DATE	CONSTRAINT DATE RATIONALE	EXCLUSIVITIES
Belgium	18-Nov-2021	It is based on the expiry date of Data + Marketing Exclusivity	Data + Marketing exclusivity in Belgium expires on 18-Nov-2021, 8+2 years from the notification of first marketing authorization in EEA on 18-Nov-2011.
USA	03-May-2026	It is based on the expiry date of the Orphan Drug Exclusivity	New Chemical Entity exclusivity expires on 03-May-2024. tafamidis meglumine has unexpired 1 NEW CHEMICAL ENTITY (03-May-2024) and 1 ORPHAN DRUG EXCLUSIVITY (03-May-2026) exclusivities in the Orange Book.
Italy	17-Nov-2026	It is based on the expiry date of an SPC	Data + Marketing exclusivity in Italy expires on 18-Nov-2021, 8+2 years from the notification of first marketing authorization in EEA on 18-Nov-2011. The earliest SPC in Italy expires on 17-Nov-2026.

3. Find patent challenges already filed in the USA

Go to the **US patent challenges** tab to learn details of existing patent challenges in this country.

tafamidis meglumine Alert

PRODUCT KEY INSIGHTS | API MANUFACTURERS | REGULATORY FILINGS | APPROVALS | CONSTRAINT DATE | PATENTS & SPCs | **US PATENT CHALLENGES** | DEALS | COMPETITIVE INSIGHTS | R&D | SCIENTIFIC

LAUNCHES & PACK PRICES | US MARKET SHARE | LATAM MARKET SHARE

Summary

Orange Book Patents for VYNDAQEL, Capsule, NDA - 211996

7214695 | 7214696 | 8168663 | 8653119

Related Products

No Related Products with US Patent Challenge information

No US patent challenges have been filed yet. However, *US patent challenges* tab is updated within 24-48 hours after news have been announced so it's highly recommended to set up an alert.

Anticipate and plan generic launches

- When can I expect a product to lose exclusivity? Dates are listed in Constraint Date Forecast & Exclusivity tab.
- Has anyone else already filed US patent challenges? No, no one has filed US patent challenges yet.

tafamidis meglumine Alert

PRODUCT KEY INSIGHTS | API MANUFACTURERS | REGULATORY FILINGS | APPROVALS | **CONSTRAINT DATE** | PATENTS & SPCS | US PATENT CHALLENGES | DEALS | COMPETITIVE INSIGHTS | R&D | SCIENTIFIC

LAUNCHES & PACK PRICES | US MARKET SHARE | LATAM MARKET SHARE

Filters: Country/Territory (3)

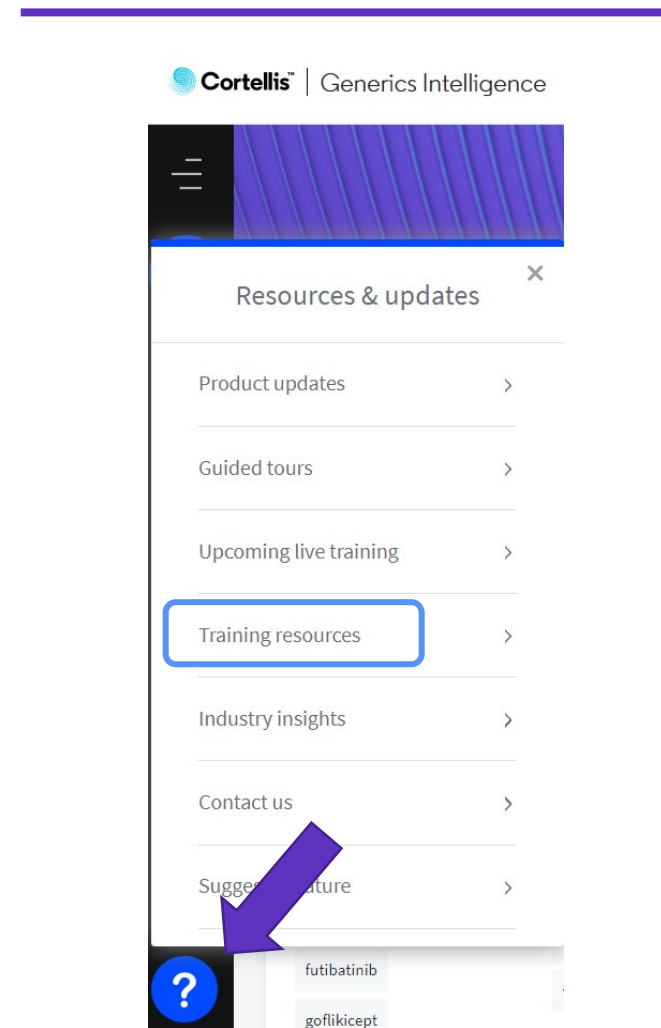
There are no patent challenges in the US for this product yet as NCE exclusivity is preventing them for a couple of years.

Constraint Date Forecast & Exclusivities Customize Columns Export Showing 1-3 of 3

COUNTRY/TERRITORY ↑	CONSTRAINT DATE ↑	CONSTRAINT DATE RATIONALE	EXCLUSIVITIES
Belgium	18-Nov-2021	It is based on the expiry date of Data + Marketing Exclusivity	Data + Marketing exclusivity in Belgium expires on 18-Nov-2021, 8+2 years from the notification of first marketing authorization in EEA on 18-Nov-2011.
USA	03-May-2026	It is based on the expiry date of the Orphan Drug Exclusivity	New Chemical Entity exclusivity expires on 03-May-2024. tafamidis meglumine has unexpired 1 NEW CHEMICAL ENTITY (03-May-2024) and 1 ORPHAN DRUG EXCLUSIVITY (03-May-2026) exclusivities in the Orange Book.
Italy	17-Nov-2026	It is based on the expiry date of an SPC	Data + Marketing exclusivity in Italy expires on 18-Nov-2021, 8+2 years from the notification of first marketing authorization in EEA on 18-Nov-2011. The earliest SPC in Italy expires on 17-Nov-2026.

Need more guidance?

Go to Training resources via the question mark inside **Cortellis Generics Intelligence** to access quick reference cards, short videos and recorded sessions.





**To login to Cortellis
Generics Intelligence
[click here.](#)**

