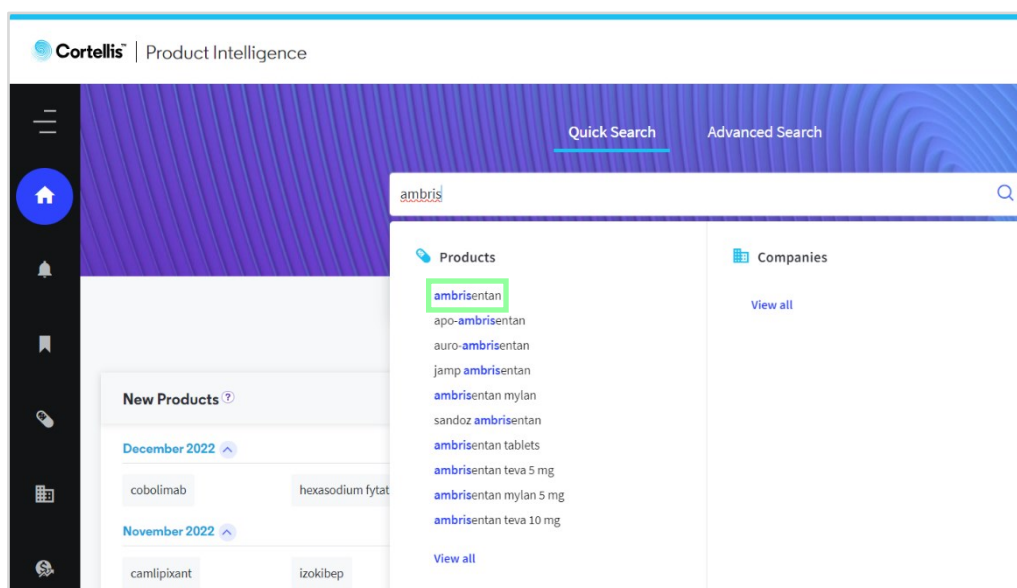


Identify patent and exclusivity data for a molecule

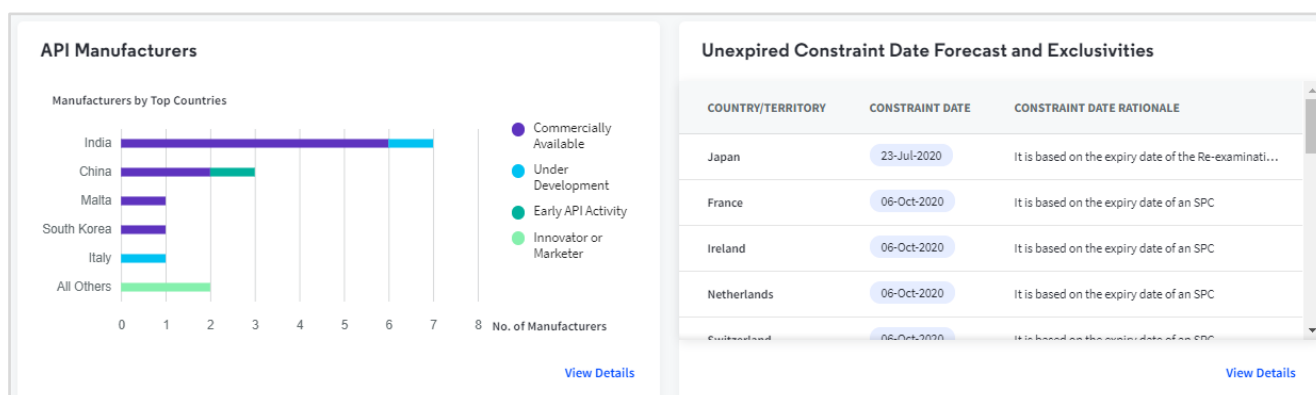
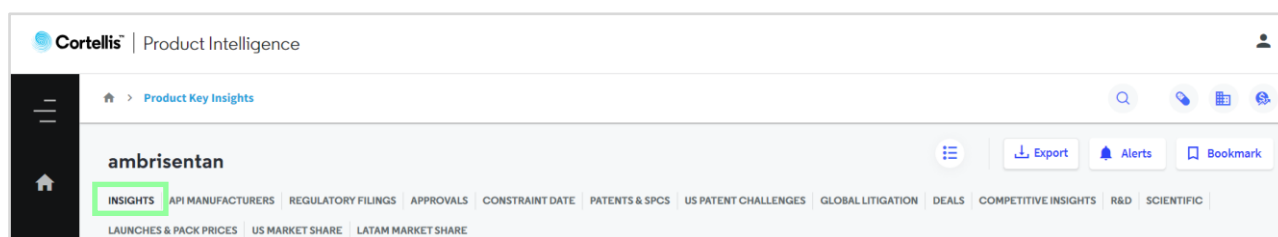
This Quick Reference card will help you discover different patents and exclusivity data protecting ambrisentan as well as the day when is more likely to find generic launches in several countries.

From the homepage in Cortellis Product Intelligence go to Quick Search and type 'ambrisentan'. Suggestions will be listed at the bottom of the field, click **ambrisentan** to access its profile.



Once in the **Product Key Insights** scroll down to visualize top patent countries and Constraint Date Forecast information.

If there are unexpired exclusivities, the **Unexpired Constraint Date Forecast and Exclusivities** table will display **constraint dates and rationale** behind them. This data helps you anticipate the date when generic launches are expected in more than 30 countries around the world.



Click **View details** to navigate to **Constraint Date Forecast** and display all countries where this data is available. **Constraint Date Forecast & Exclusivities** table can be sorted when clicking the headings. The following table has been **sorted** in chronological order showing countries where generics are expected further in the future at the top.

Product Key Insights > Constraint Date Forecast & Exclusivities

ambrisentan

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

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

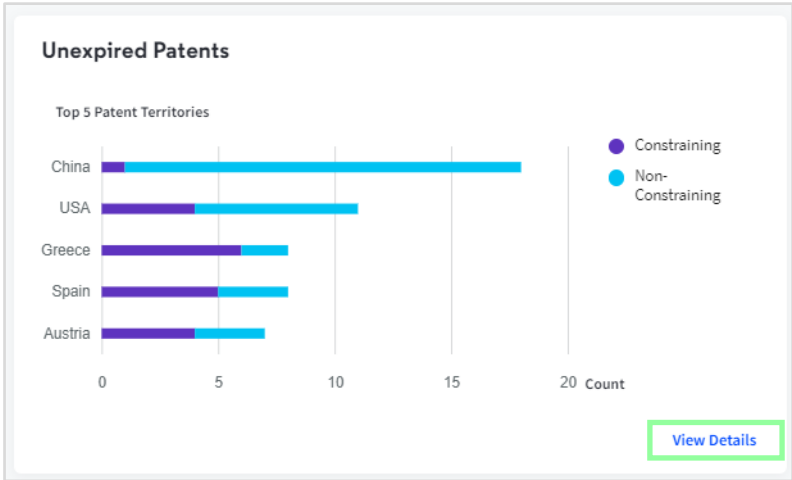
Constraint Date Forecast & Exclusivities ⓘ

Filters Country/Territory

Customize Columns | Export

Rows per page: 10 1-10 of 36

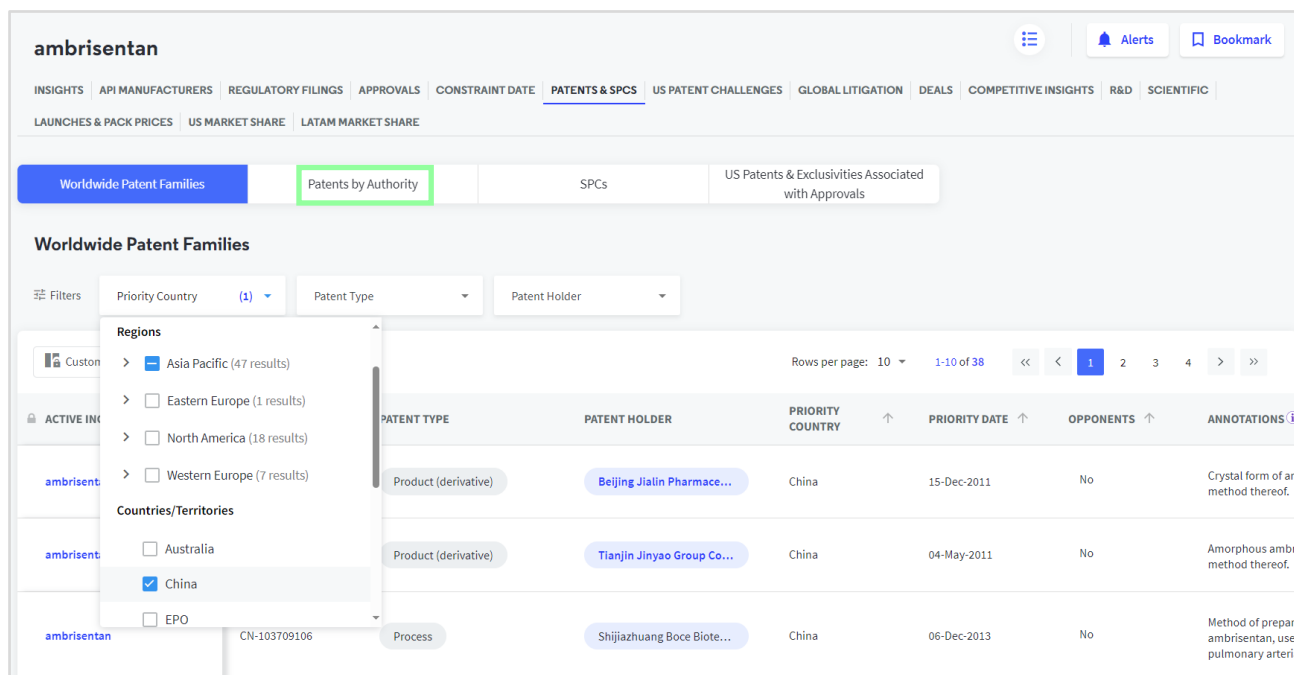
COUNTRY/TERRITORY ↑	CONSTRAINT DATE ⓘ ↓	CONSTRAINT DATE RATIONALE	EXCLUSIVITIES
Croatia	13-Oct-2020	It is based on the expiry date of an SPC	The earliest SPC in Croatia has expired. Data exclusivity in Croatia has expired.
Greece	08-Oct-2020	It is based on the expiry date of an SPC	Data exclusivity in Greece has expired. The earliest SPC in Greece has expired.
Austria	07-Oct-2020	It is based on the expiry date of an SPC	The earliest SPC in Austria has expired. Data exclusivity in Austria has expired.



Patent information can be found at the bottom of the Product Key Insights. This bar chart will help you identify top countries where patents (constraining and not) are still unexpired. Click **View details** to navigate to Patents Tab.

This tab provides data gathered and indexed by Cortellis Patents team helping you quickly identify the type of innovation they are protecting (product, new use, process, formulation, etc) as well as **patent details**, Estimated expiry dates, patent holders, SPCs and more.

As other tables in Cortellis Product Intelligence, **Patents by Authority** table can be filtered, **exported** and sorted when clicking the headings. Columns can be hidden or displayed from the **Customize Columns** button. The following table presents product patents China **sorted** in chronological order.



PATENT TYPE	PATENT HOLDER	PRIORITY COUNTRY	PRIORITY DATE	OPPONENTS	ANNOTATIONS
Product (derivative)	Beijing Jialin Pharmace...	China	15-Dec-2011	No	Crystal form of ambrisentan, method thereof.
Product (derivative)	Tianjin Jinyao Group Co...	China	04-May-2011	No	Amorphous ambrisentan, method thereof.
Process	Shijiazhuang Boce Biote...	China	06-Dec-2013	No	Method of preparing ambrisentan, useful for pulmonary arterial hypertension.

Companies names in Cortellis Product Intelligence are hyperlinked allowing you to navigate to their profile and evaluate their Corporate API rating or regulatory filings, for example.

Glossary:

Constraint Date Forecast is a proprietary algorithm considers patents, market exclusivities and data exclusivities for a specific product in a specific country and estimates the earliest date that a generic could enter the market when the product loses patent or exclusivity protection The "Constraint Date Forecast" is useful to consolidate patent expiry information for targeting products and should not be taken as a definitive date.

PATENT TYPES

- **Analyte** - Patents disclosing an analytical method to determine the drug, including determining its concentration in the body or a body fluid.
- **Component of combination** - Includes all instances where the invention is primarily concerned with the use of a drug in any combination with another drug, whether synergistic or not. This term is only used if the patent is primarily concerned with the drug combination.
- **Constraining** - Constraining patent(s) are those which are most likely to prevent generic competition or may not be easily circumvented.
- **Delivery device** - This term is for non-consumable devices only. Delivery systems such as controlled-release tablets or suppositories would be defined as "Formulations".
- **Drug target** - Used for receptors, enzymes etc. which are claimed in the patent, and which were used to identify a drug.

- **Formulation** - All types of formulation of a drug, including those where the active compound is chemically modified (e.g. prodrugs or immunoconjugates). Only used for patents that are predominantly concerned with a particular formulation. A prodrug is an inactive form of a known drug; it has no medicinal effect itself, but is activated in the body metabolism and breaks down to produce the active drug.
- **General Interest** - Drugs not directly covered by a patent but that are certainly of interest to someone looking for patents about the drug. Examples are patents claiming ways of overcoming resistance to a drug, or claims to the drug screening method. This term is also used for biotechnology applications where it can be difficult to decipher the relationship between a patent and its commercial application.
- **New Use** - Methods of using a drug, usually for a new indication.
- **Process** - Used for patents predominantly concerned with the preparation of a drug.
- **Process (intermediates)** - Used where the patent discloses a method for producing an intermediate without claiming a process for producing the drug itself.
- **Product** - Usually the product patent is the first one to be associated with a drug. For drug combinations, the term "Product" is assigned to each patent claiming one of the components as well as to the patent claiming the combination.
- **Product (derivative)** - Used for patents claiming novel salts, stereoisomers, crystal form and polymorphs. The term "derivative" is not used in a chemical sense, i.e. it does not cover analogues of a drug which are directly chemically modified. Note that patents claiming prodrugs of a drug are linked as "Formulation" to that drug.
- **Tentative** - Used if there is a strong likelihood that a patent refers to a compound but the information available about that compound is not clear enough to make a decision. This is usually only applied to drugs at early development stages, when the structure of the drug is not publicly available.

Corporate API Rating as proprietary analytic that indicates how capable the corporate group is of supplying bulk API to regulated markets, i.e. Western Europe and North America. This pertains to all API the company manufactures and not just the molecule in the specific API reports. There are 6 different levels of Corporate API rating, shown next:

- **Big Pharma** -Innovative companies with at least \$1.0B USD in annual R&D expenditures
- **Established** -Companies with years of experience supplying active ingredients to regulated market.
- **Less Established** -Less of a track record in supplying to regulated markets, either in terms of years of history or number of products supplied. Still considered as capable of supplying regulated markets.
- **Potential Future** -Interest in supplying regulated markets, but with limited or no known performance.
- **Local** -Supplying only to their local and other less-regulated markets; do not currently have the capability of passing inspections by regulatory bodies like the US FDA.
- **Unrated** -Companies for which Cortellis Product Intelligence has not assigned a rating.

For more information contact Customer Service at [**LS Product Support**](#)