



High Barrier Packaging:
The key to longer shelf
life for OSD formulations.



The global pharmaceutical packaging market size was valued at USD 127.83 billion in 2022 and is expected to register a compound annual growth rate (CAGR) of 9.7% from 2023 to 2030. The U.S. accounted for the largest pharmaceutical market worldwide.¹

The US pharmaceutical and nutraceutical manufacturers have traditionally dispensed oral solid dosages in bottles, with only about 20% of OSD formulations packed in blister formats. This trend is changing away from bottles and towards blisters due to several factors, including child safety, product quality, medication adherence, and sustainability. As a result, the market for blister packaging in the US is expected to grow by 5.6% CAGR compared to 3.5% CAGR for bottles from 2022 to 2028.¹

A few significant reasons of this shift from bottles to blisters are explained below:

Contamination: Blister packaging effectively reduces the risk of contamination through unit dose dispensing and maximizes shelf life by preventing ingress of moisture and oxygen.

Dosing: Blister packaging allows for individual dispensing of capsules and tablets, which makes it easy to track the dosing and request refills more on time.

Child-Resistant and Senior-Friendly Openings: Child-resistant bottle caps can be difficult for seniors to open, while blister packaging can be designed to accommodate a variety of accessibility needs.

Right Sizing: Medications in bottles can rattle and break, which can reduce efficacy and accuracy. Blister packs provide snug protection for each capsule or tablet in single cavity using optimum material and preventing waste.

Convenience to carry: Blister packs are compact and portable, making them easier to store and transport than pill bottles.

With a wide range of blister packing materials offering various barrier properties available in the market, selecting the right barrier packaging material becomes crucial to ensure potency and enhanced shelf life for highly sensitive formulations in blister packs.

Introduction to high barrier films

The US pharmaceutical and nutraceutical industry today, is more focused on novel molecule research, formulation development, and subsequent clinical trials. As with the other phases of product development, packaging development also presents its own set of challenges. A well-formulated drug with a good efficacy has no use if the packaging does not maintain the drug's activity until it reaches the patient. Today, the role of packaging is expanding well beyond only protection and maintenance of product integrity.

The industry has increasingly considered packaging as a way to reduce drug development costs in recent decades. Companies are now adopting new packaging systems that are both regulatory compliant and patient friendly. Additionally, there is a growing demand for packaging solutions that can extend product shelf life and maintain product integrity during distribution.

Ultrahigh barrier packaging is a type of packaging that provides the highest level of protection against environmental factors, such as, moisture, oxygen, and light. This makes it ideal for packaging formulations that are sensitive to these factors.

There are several reasons why ultrahigh barrier packaging is becoming increasingly popular among pharmaceutical and nutraceutical manufacturers.



These include:

-  The need to pack drug products containing moisture-sensitive ingredients.
-  The need to pack drug products containing molecules that are susceptible to oxidative degradation.
-  The need for a single packaging solution for a drug product that is intended for distribution across various climatic zones.
-  The need for extension of shelf life considering consumer usage pattern or extended logistic distribution period.

This guide explains ACG's ultrahigh barrier packaging solutions for some of the most sensitive formulations in pharmaceutical and nutraceutical space.

Ultrasafe

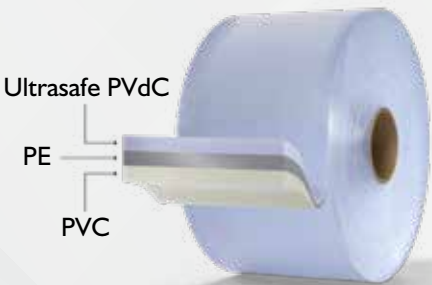
Ultrasafe is an ultra-high barrier thermoformable film which is manufactured by coating pharmaceutical grade polyvinyl chloride (PVC) with Solvay's Diofan® Super B polyvinylidene chloride (PVdC). Diofan® Super B, a superior grade of PVdC is a unique co-polymer which imparts Ultrasafe its exceptional moisture and oxygen barrier.

The most used laminate structure for Ultrasafe is a trilaminate structure, where rigid PVC is laminated to PE and coated with Diofan® Super B. As the thickness and weight of Diofan® Super B PVdC coating increase, the overall barrier properties are also enhanced. This technology offers a significant degree of customisation and flexibility as compared to alternative traditional high barrier solutions in the market.



Ultrasafe: Laminate Structure

Ultrasafe is available in three laminate structures with various Diofan® Super B PVdC coating options.



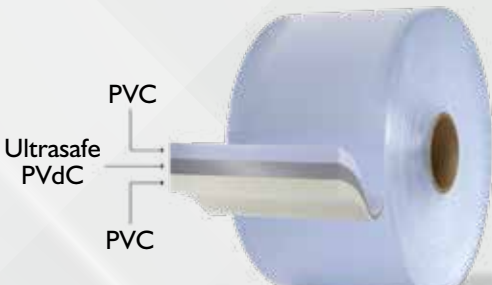
ULTRASAFE TRIPAC

SUPER B BASED PRODUCTS	STRUCTURE
PVC/PE/Diofan® Super B	250/25/90
PVC/PE/Diofan® Super B	250/25/120
PVC/PE/Diofan® Super B	250/25/180



ULTRASAFE DUPAC

SUPER B BASED PRODUCTS	STRUCTURE
PVC/Diofan® Super B	250/90
PVC/Diofan® Super B	250/120

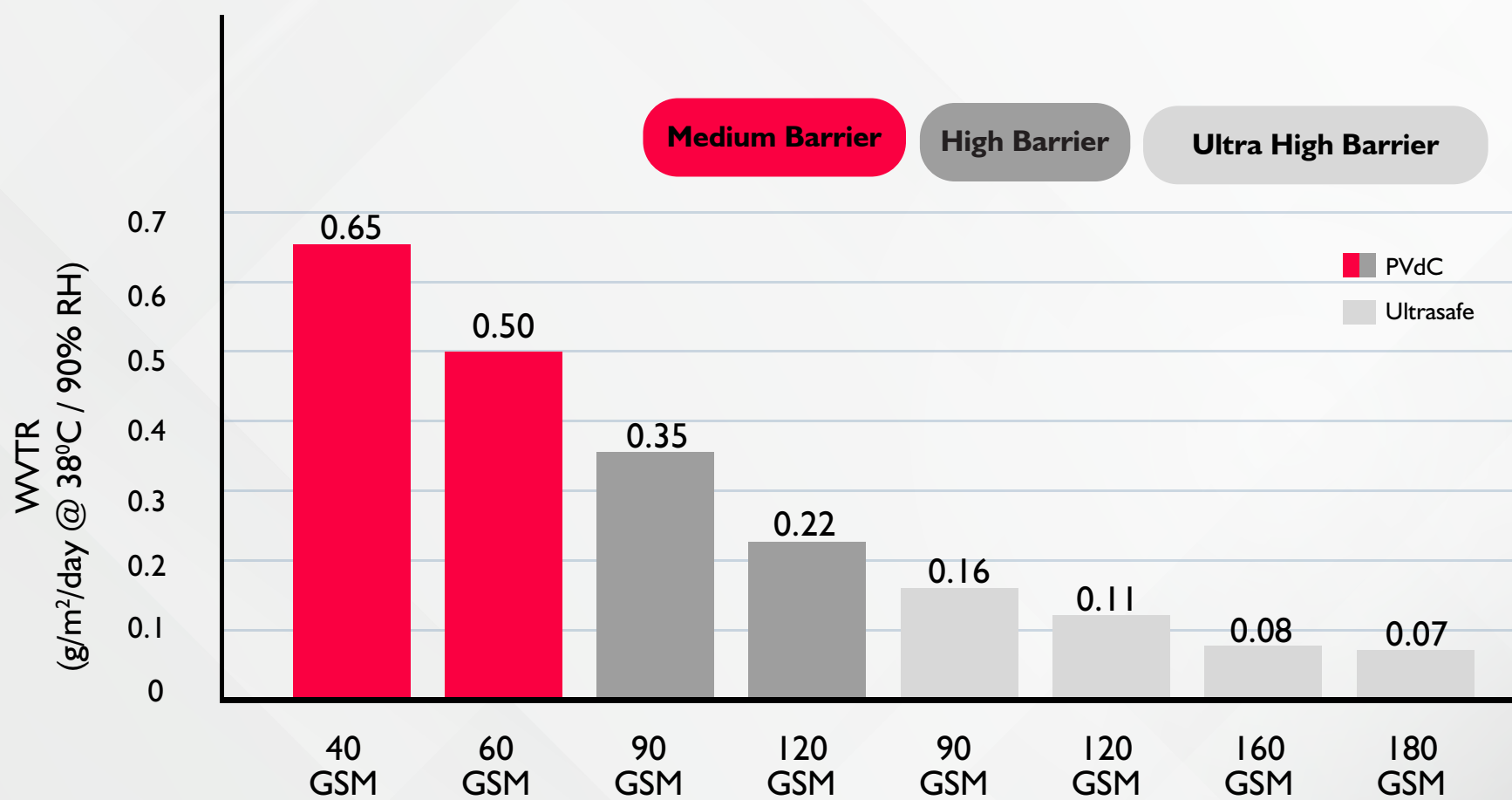


ULTRASAFE CORE

SUPER B BASED PRODUCTS	STRUCTURE
PVC/PVdC/Diofan® Super B	120/120/130
PVC/PVdC/Diofan® Super B	120/180/130

Water Vapour Transmission Rate: Regular PVdC vs Ultrasafe PVdC

A one-to-one comparison of moisture barrier properties of a regular PVdC with Diofan® Super B PVdC (ACG’s Ultrasafe film) for similar weightage of PVdC coatings shows a significant reduction in moisture permeability as the weightage of Diofan® Super B PVdC coating increases in Ultrasafe film.



Unmatched barrier protection against oxygen and moisture.

Offers barriers against any external aromas & flavours.

Well suited for highly sensitive formulations and probiotics.

Available in a wide range of colours.

Forms well in different packaging lines without any tooling modifications.

Has good seal integrity and is scratch and abrasion-resistant.

Excellent thermoformability allows high pill density and smaller pack sizes, leading to cost optimization in production, storage and transport.

**Ultrasafe:
Features & Benefits**

Alumpack

Aluminium-based packaging materials are known to offer the ultimate barrier to highly sensitive formulations in pharmaceutical and nutraceutical applications. ACG's Alumpack is an aluminium packaging material for blister applications.

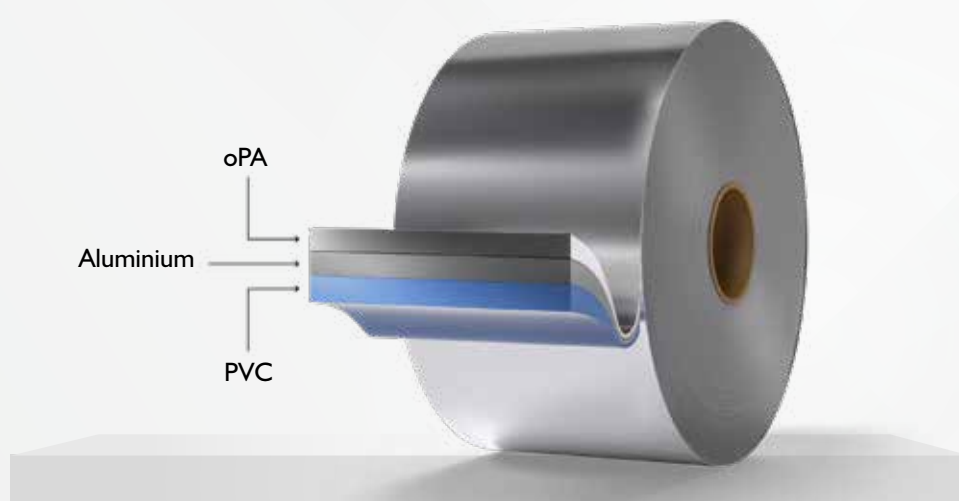
Aluminium is laminated with oPA (BOPA or nylon) on one side and PVC on the other side. This laminate structure is called a cold-form film or cold-form blister foil due to the blister-forming technique in which the laminate is pressed into a mould without applying heat. The cavities of the blister are created using plugs during the blistering process.

This aluminium laminate is then sealed with aluminium foil to form an Alu-Alu blister.



Alumpack: Laminate Structure

The most widely used specification of Alumpack films for oral solid dosage in pharma is oPA/Al/PVC. The oPA layer provides the elasticity to form smooth, unbroken cavities for the drug product. Aluminium offers the protective barrier, and PVC acts as a sealing substrate for the base and lidding foil. A variant of this structure has an additional primer layer in between oPA and aluminium that enhances the bond in the laminate offering delamination resistant Alu-Alu blisters.



Alumpack with 4 layers:

A 4-layer Alumpack is recommended for formulations that are brittle or need extra protection against breaking in the blister cavity. The additional PVC layer on top of oPA offers rigidity and toughness to the blister pack, reducing the possibility of dents and damage to the product inside the cavity due to external abrasion.

Sustainable Coldform foils

Increasingly, manufacturers are moving towards using more sustainable raw materials for their drug products, including packaging materials. Alumpack is available in PVC free laminate structure, offering eco-friendly alternative to traditional Alu-Alu films, without compromising on its barrier protection properties.

Alumpack: Features & benefits

The ultimate barrier against moisture, light & oxygen.

Ideal for highly sensitive formulations.

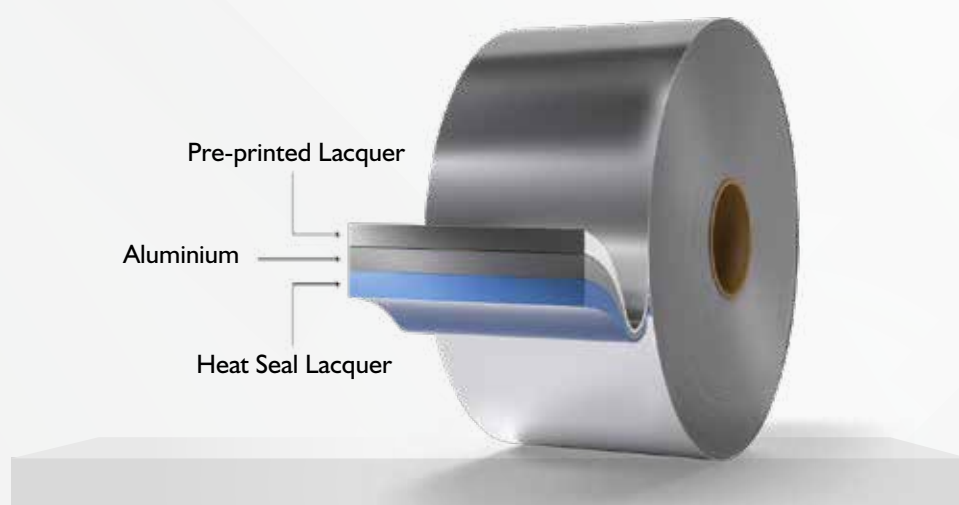
Excellent formability and seals to different types of lidding foil.

Primer-grade aluminium laminates ensure higher resistance to delamination.

Vibrant surface or reverse printed cold-form blister options available for brand security & aesthetic appeal.

Alumlid – Lidding foil

Aluminium foil is used as a lidding material in blister packs owing to its strong barrier and easy-to-tear properties. The most basic construction of an aluminium lidding foil for blister application consists of three components as shown in the figure:



The print primer ensures clear and consistent printability on the lid foil. Aluminium provides the barrier protection to the blister heat seal lacquer offers the sealing layer to the base film.

Three important parameters to check while selecting a lidding foil for your blister pack:



Seal strength: The lidding foil must be able to seal tightly to the blister cavity, preventing the product from falling out.



Printability: If the lidding foil is to be printed, the print primer on the lid foil must be compatible with the printing process and the ink that will be used.



Child Safety: Child resistant foils is designed to be opened by adults but difficult to open by children. This prevents children from accidentally accessing the medication or other harmful substance.

Child Resistant & Senior Friendly Lid foil

Child resistant – senior friendly lidding foils are gaining prominence in the United States in order to improve the child safety factor for their drug product, cannabis infused products as well as nutraceuticals. Depending on safety requirements, there are different lidding foil opening options offered by ACG's child resistant foils.

Push Through: This is the most common format of lidding foil. With this type of lidding foil, the drug product is dispensed by pushing it through the lidding foil. A child resistant push through lid foil requires greater force to open compared to a regular push through lid foil, making it difficult to open by children yet an easy open for an adult.

Peelable: The drug product is dispensed by peeling the lid foil off the base film. Most suitable for products that are brittle or fragile and may break when exposed to some pressure while opening the blister.

Peel Push: This lidding foil format has two step opening. First the paper is peeled off to reveal an aluminium lidding foil, which is then pushed through to dispense the drug product.

Cut open using scissors: For this type of lidding foil, the drug product can be dispensed only by cutting the blister open using a scissor.

Conclusion:

Ultra-high barrier films are gaining popularity in the pharmaceutical as well as nutraceutical industry owing to their ability to provide ultimate protection to the formulation against environmental factors, thereby boosting their shelf lives.

With a variety of packaging options available on the market, packaging specialists may still face a challenge selecting the right kind of packaging for their formulations considering the pressing timelines for development and launch. With over six decades of catering to pharmaceutical and nutraceutical manufacturers, ACG is a leading global supplier manufacturing a wide range of thermoformable and cold forming barrier packaging materials for oral solid dosage forms. With two global manufacturing locations, our team of experts support our customers select the right packaging for their formulations and offer technical and commercial assistance to scale and optimize their production.

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