



## MÜV™ THC (72 Hour Extended Release)

### Transdermal Patches

20 mg THC

20 mg CBD

10 mg THC and 10 mg CBD (1:1)



POWERED BY  
müv™

## Dose

**THC DOSE:** One Patch delivers 20 mg THC and <2 mg CBD

**CBD DOSE:** One patch delivers 20 mg CBD and <2 mg THC

**THC/CBD (1:1) DOSE:** One Patch delivers 10 mg THC and 10 mg CBD

**TOTAL PRODUCT DOSES:**

1 Patch (18 cm<sup>2</sup>)

## MÜV Evolve Encapsulation For Transdermal Cannabis

Because cannabinoids are fat-soluble their ability to get into the water-based bloodstream through the skin is minimal - this has been the main challenge for cannabis topicals seeking full-body effects. Evolve Encapsulated Technology is the solution to this problem.



This proprietary process uses FDA-approved ingredients to encapsulate the cannabinoids in a gel format and makes them more water-soluble. This allows the cannabinoids to deliver a controlled 72-hour release. The encapsulation technology also allows the user to wear the patch anywhere on the body for discreet and hassle-free symptom management.

\*Patient Information

## Introduction

This pamphlet provides a summary of information about MÜV™ (72 Hour Extended Release) Transdermal Patches\*. Please read this pamphlet thoroughly and keep it with your medicine. If you have any questions, please consult your physician.

MÜV THC Transdermal Patch contains 20 mg active ingredient extracted and distilled from *Cannabis* spp. plants meticulously grown without the use of pesticides.

**IMPORTANT: Your physician has recommended this medication for your use only. DO NOT LET ANYONE ELSE USE IT. KEEP THIS MEDICINE OUT OF THE REACH OF CHILDREN AND PETS.**

If a child puts patch on skin or in mouth, remove immediately and contact a poison control center. Do not drive a car or operate heavy machinery until you know how this medication affects you. While taking this medication, do not drink alcohol or take other drugs that have an effect on the central nervous system, such as antidepressants or sleep aids.

Unless advised by your physician, do not use this drug if you are pregnant or nursing.

## Clinical Pharmacology

The endocannabinoid system is a series of receptors located throughout the body, which control important biological functions. Your body produces its own endocannabinoids, and cannabinoids like  $\Delta^9$ -tetrahydrocannabinol (THC) and cannabidiol (CBD) engage these receptors to produce various effects that can promote symptom relief. THC is an agonist of the CB<sub>1</sub> receptor located throughout the central nervous system (CNS) and brain. For this reason, THC is known as the psychoactive cannabinoid, which can produce euphoria or the “high” commonly associated with cannabis use. THC is also a partial agonist of the CB<sub>2</sub> receptor system, so drug interactions with this target should also be considered. CB<sub>1</sub> receptors are located throughout the central nervous system (CNS) and brain; while CB<sub>2</sub> receptors are associated with the immune and gastrointestinal (GI) systems and also found in the brain but not as densely as CB<sub>1</sub> receptors. CBD works indirectly, as an antagonist, on the CB<sub>1</sub> and CB<sub>2</sub> receptors by interacting with other receptors to disrupt endocannabinoid function and binding. Because of its unique mode of action, CBD is non-psychoactive and can even reduce the side effects of THC.

Transdermal administration of THC can produce euphoria that accompanies other delivery methods (inhaled, oral, sublingual, etc.), but effects can vary person to person. Typically, transdermal delivery of THC does not produce the same level of euphoria when delivered via other dosing methods. Unlike oral dosing, transdermal delivery negates the

hepatic first-pass effect and minimizes the metabolic byproduct, 11-hydroxy THC, which has significantly higher psychoactivity than its predecessor, THC.

The EnCaps Encapsulation Technology used in this product is a patent-pending encapsulation of cannabis-derived compounds using FDA-approved ingredients that quickens onset time and improves the overall bioavailability of cannabinoids. Common effects of THC include euphoria, relaxation, sedation, increased appetite, and nausea reduction while side effects can include decreased blood pressure, anxiety, or paranoia. Lethal overdose has never been reported with THC or cannabis use.

Due to CB<sub>1</sub> activity in the cerebral cortex, hypothalamus, and other regions of the brain and spinal cord, THC can regulate neurological pain reception. THC has been shown to be effective as conventional opiate treatments for pain reduction and analgesia (Noyes et al. 1975; Maurer et al. 1990; Hosking and Zajicek, 2008). Clinical evidence has also shown THC to be effective in pain management and muscle spasticity/spasms especially in multiple sclerosis (MS) and other chronic pain conditions (Darmani, 2001; De Petrocellis et al. 2000). Inflammation and pain can be alleviated locally or systemically (whole-body) via transdermal application of THC, which have provided remission of inflammatory bowel diseases such as Crohn's (Naftali et al. 2013). Clinical data has also proven THC to be effective for appetite stimulation in patients with human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS). Additionally, THC acts as an anti-emetic and stimulates appetite for cancer patients undergoing chemotherapy treatments.

Sleep is an important aspect of palliative care and quality of life; and anandamide, a naturally occurring human endocannabinoid, has been shown to illicit sleep responses and improve REM sleep (Murillo-Rodrigueza et al. 1998). Anandamide activates CB<sub>1</sub> receptors, and similarly, THC significantly decreases the time it takes to fall asleep, and once asleep THC led to fewer awakenings during the first half of the night (Cousens and DiMascio, 1973; Nicholson et al. 2004).

There are numerous targets for CBD, but the earliest studies have shown potent neuroprotective properties through antioxidant properties and improvement of certain neurodegenerative disorders (US Patent; Liput et al. 2013). Potent anti-epileptic effects have been demonstrated clinically for particular forms of epilepsy with neuronal protection in the hippocampus (GWPH Trials). Inflammation can be alleviated locally or systemically (whole-body) via transdermal application of CBD (Lodzki et al. 2003). Due to its interaction with hydroxytryptamine serotonin receptors, CBD has anti-anxiety and anti-depressant effects (de Mello Schier et al. 2014). These indications have also been corroborated with social anxiety disorders (Bergamaschi et al. 2011) and THC-

induced psychosis (Zuardi et al. 1982; Bhattacharyya et al. 2010). The anti-inflammatory effects of CBD coupled with the location of CB<sub>2</sub> receptors in the GI system could provide relief for certain inflammatory bowel diseases (Esposito et al. 2012).

Using defined ratios of THC and CBD leads to what is known as the cannabis "entourage effect" which leads to synergistic effects between compounds that would otherwise not be present with individual treatment. A 1:1 ratio of THC and CBD therefore has both the effects of THC (euphoria, appetite stimulation, pain reduction) as well as CBD (for anxiety, inflammation, and spasticity improvement). Studies have shown that this ratio does not significantly attenuate the effects of THC suggesting no significant decline in cognitive function with this ratio (Jacobs et al. 2016). Clinical trials have shown that co-administered THC and CBD (1:1) demonstrated a marked improvement in sleep quality for conditions ranging from multiple sclerosis, neuropathic pain, intractable cancer pain, and rheumatoid arthritis (Russo et al. 2007).

## Indications and Use

MÜV (72 Hour Extended Release) Transdermal Patches can be used for both acute and chronic conditions due to its fast-acting nature and sustained drug release properties. Additionally, the high lipid solubility of the cannabinoids can create a "reservoir effect" in the stratum corneum of the skin (Touitou and Fabin, 1988) and provide longer sustained delivery times of THC and CBD. Conditions for use include: cancer, glaucoma, HIV and AIDS, MS, hepatitis C, amyotrophic lateral sclerosis (ALS), Crohn's disease, Parkinson's disease, or any other debilitating medical condition that a physician believes would outweigh the potential risks for a patient. It can also be used as a palliative care treatment due to its improvements on general outlook including pain, spasticity, weight loss, anxiety, and sleep promotion.

## Dosage and Administration

When starting a new dosing regimen, it is crucially important that medication is administered in small doses (known as titrating) to determine an effective dose and to minimize side effects. One patch (5.0 cm x 3.6 cm) constitutes one dose, and the patch cannot be cut or punctured. However, the patch can be removed and effects will dissipate within 15 minutes; the patch can be reapplied to the skin and medical tape can be used to affix a patch that is loose on skin.

Common application sites for MÜV Transdermal Patches include the upper arm, chest, abdomen, or any venous region with minimal hair. Prior to use, clean the application site with soap and water or rubbing alcohol, ensure that the skin is dried and

intact before applying patch. Remove the clear liner to expose the adhesive (sticky) side of the backing and press patch firmly in place and hold using the palm of the hand for 30 seconds to ensure uniform adhesion. Typical onset time for MÜV (72 Hour Extended Release) Transdermal Patches are less than 30 minutes and delivery continues through 72 hours. Wear patch throughout dosing period; warm water (such as a hot shower) will help facilitate patch removal. Rubbing alcohol can be used to remove excess adhesive during application or after patch removal. Change application areas every three days if a new patch is to be applied.

## Contraindications

Patients known to be allergic to cannabis should not use cannabis products.

Relative contraindications include: coronary heart diseases, hypotension, drug abuse, alcohol abuse, mania, depression, bipolar, schizophrenia, or a prior negative reaction to cannabis.

## Warnings and Precautions

**Be sure to notify your physician if you have any of the following:**

- Have or had history of heart disorders because of occasional low blood pressure, high blood pressure, rapid heart rate, palpitations, or fainting;
- Present or past issues with drug abuse;
- Present or past issues with alcohol abuse;
- Have or had mental health problems (depression, mania, bipolar, or schizophrenia);
- Present or past history of epilepsy, seizure disorders, and/or seizure-like activity;
- Have any allergies to drugs;
- Are pregnant or nursing, or intend to become pregnant.

If you become pregnant while taking any MÜV cannabis-infused product, stop using immediately and consult with your physician.

MÜV (72 Hour Extended Release) Transdermal Patches should be used with caution, particularly with children and elderly patients, as there are few studies in these patient populations. A physician should monitor children under the age of 18 closely as THC can have adverse effects on brain development.

When consulting with your physician, please include all current medications (both prescription and non-prescription) as MÜV Transdermal Patches can theoretically interact with other drug therapies. Avoid grapefruit or grapefruit juice and other CYP450 inhibitors as these can adversely affect THC treatments. Adverse reactions could also occur with alcohol and other drugs that affect the CNS (such as Valium, Librium, Xanax, Seconal, Nembutal, or Phenobarbital).

## Adverse Reactions

**Tell your physician if any symptoms persist or worsen with time:**

- Cardiovascular: palpitations, tachycardia, vasodilation, hypotension (low blood pressure);
- Digestive: dry mouth, abdominal pain, nausea, vomiting, diarrhea, constipation, anorexia, excessive appetite, hepatic enzyme elevation;
- Nervous System: euphoria, drowsiness, memory loss, confusion, anxiety, paranoia, depersonalization, hallucinations, poor balance, dizziness, somnolence, nightmares, depression, difficulty speaking;
- Musculoskeletal: myalgias;
- Skin: flushing, sweating, irritation at application site;
- Ocular: conjunctivitis, impaired vision;
- Body: chills, headache, fatigue;
- Respiratory: cough, rhinitis, sinusitis.

**INACTIVE INGREDIENTS (All USP or Pharma-grade):** Water, Ethanol, Acrylates Adhesive, Diethylene Glycol Monoethyl Ether, Polysorbate 20, and Hydroxyethyl Cellulose within an Ethylene Vinyl Acetate Membrane and Polyethylene Backing.

## FAQ's

### **DO ATLAS THRIVE TRANSDERMAL PATCHES HAVE PSYCHOACTIVE EFFECTS?**

Two of the Thrive Transdermal Patches are psychoactive: MÜV THC & MÜV 1:1.

### **HOW ARE THC AND CBD RELEASED INTO THE BLOODSTREAM?**

THC and CBD are fat-soluble, so they can only penetrate the upper levels of the fatty dermis, resulting in localized pain relief. The EnCaps™ encapsulation technology utilizes a water-soluble gel to create a little envelope in which THC and CBD transfer through the lipid membranes, like human skin, to reach the bloodstream. Once the shuttle hits the bloodstream, the cannabinoids are released, resulting in fast-acting, systemic effects.

### **HOW LONG CAN THE PATCHES BE WORN?**

Each patch can be worn for 72 hours. You can wear this consistently across that time period, or you can remove the patch as needed—just put the patch back on the plastic vessel it came in.

### **WHAT IS THE ADHESIVE MADE OUT OF?**

NON-DMSO.

### **HOW MANY MG OF ENCAPSULATED CANNABINOIDS ARE IN EACH PATCH?**

MÜV THC—20 mg of THC

MÜV 1:1—10 mg of THC & 10 mg of CBD

MÜV CBD—20 mg of CBD

### **CAN IT BE WORN IN THE SHOWER, AT THE BEACH, AT THE POOL, ETC?**

Yes, the patch can be worn in the shower or at the pool or gym. If the patch seems to lose its stickiness, secure it in place with medical tape.

### **CAN IT BE REMOVED AND PUT BACK ON?**

The patch can be removed and put back on. If you place the patch back on its plastic backing from the packaging, it can be reapplied. If it seems to lose its stickiness, secure it in place with medical tape.

### **IS IT POSSIBLE THE MEDICINE MAY LAST LONGER THAN 72 HOURS?**

It is possible the Thrive patch may last longer than 72 hours, but we recommend swapping your patch out at the recommended 72 hours for consistent dosing.

## FAQs

### *HOW CAN I SWITCH FROM A CANNABIS OIL TO A PATCH?*

Atlas Thrive transdermal patches are considered a micro dose product with an approximate dose of 0.28mg/hour with a total of 20 mg of active ingredient released over a 72-hour period. For patients currently taking regular doses of ingested oils, it is recommended to check the dose equivalency based on the potency of current product they are taking. For high dosage patients, the patch may be complimentary or “stacked” with other cannabis medicines.

### *IS THE RATE OF RELEASE OF THC/CBD FROM THE PATCH LINEAR?*

Yes, the rate of release of THC/CBD from the patch is linear.

### *WHAT IS THE RATE OF RELEASE OF THC/CBD PER HOUR?*

The patch releases THC/CBD in a consistent dosage of 0.28mg/hour.

### *DOES HEAT (e.g. FROM A SHOWER, HOT TUB, BATH, BODY TEMPERATURE) INCREASE THE RATE OF RELEASE OF THE CANNABINOIDS FROM THE PATCH?*

No, heat does not have an effect on the transmission rate of the cannabinoids. The dose will remain consistent regardless of the introduction of outside heat or variations in body temperature.

### *HOW DO YOU TITRATE USING THE PATCH?*

Patients can start with having the patch applied for 4 hours the first day, then 6 hours the next day, etc.

### *WHICH AREAS OF THE BODY CAN THE PATCH BE APPLIED TO?*

The Atlas Thrive transdermal patch may be used as target therapy and/or for general relief. It can be applied to venous areas with thin skin and high blood flow, for example: on the arms, neck, back, stomach etc. Do not apply over the eyes or mouth. For wearability, it is not recommended to apply in hinge areas such as the wrist, as this can wear out the adhesive.

### *HOW CAN I MANAGE A REACTION CAUSED BY THE ADHESIVE ON THE PATCH?*

Some patients may experience mild irritation and should discontinue use if it worsens. For frequent use patients with mild skin sensitivity, we recommend switching up the application area from time to time. It's important to note that we do not use any DMSO (dimethyl sulfoxide) as the adhesive agent in this product. The adhesive agent is Acrylates Adhesive and may cause irritation for people with highly sensitive skin. It's important that users alternate the application site to reduce the likelihood of irritation.

### *COULD THE PATCH INTERACT WITH OTHER PRESCRIPTION MEDICATIONS?*

We always recommend checking with your physician first, as the results may vary by patient experience. Due to the micro dose aspect of this product, we don't anticipate any major concerns.

### *COULD THC FROM THE PATCH BE DETECTED IN BLOOD TESTS?*

Yes, as this product penetrates directly into the skin membrane, the THC from the THC and 1:1 patches would appear in blood tests.