

STATE OF TEXAS,  
*Plaintiff,*

v.

BLISS W. CLARK, M.D., P.A.  
D/B/A CLARK ORTHOPEDICS &  
REHABILITATION AND BLISS W.  
CLARK, INDIVIDUALLY,  
*Defendants.*

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IN THE DISTRICT COURT OF

285th

TH JUDICIAL DISTRICT

BEXAR COUNTY, TEXAS

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**PLAINTIFF'S ORIGINAL PETITION AND  
APPLICATION FOR TEMPORARY AND PERMANENT INJUNCTION**

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW, THE STATE OF TEXAS, Plaintiff, acting by and through its Attorney General GREG ABBOTT ("State"), and at the request of the TEXAS DEPARTMENT OF STATE HEALTH SERVICES ("DSHS") files this Original Petition and Application for Temporary and Permanent Injunction against BLISS W. CLARK, M.D., P.A. d/b/a CLARK ORTHOPEDICS & REHABILITATION and BLISS W. CLARK, INDIVIDUALLY, under the authority of the Texas Health and Safety Code (TEX. HEALTH AND SAFETY CODE ANN. §§ 431.001 *et seq.*, also referred to as the Texas Food, Drug and Cosmetic Act), and pursuant to the Texas Deceptive Trade Practices TEX. BUS. & COM. CODE ANN. §17.46 *et seq.* ("DTPA"), and in support thereof would respectfully show the Court the following:

**DISCOVERY CONTROL PLAN**

1. Discovery shall be conducted under LEVEL 2 in accordance with Rule 190.3 of the Texas Rules of Civil Procedure.

**PLAINTIFF**

2. This suit is brought by Attorney General GREG ABBOTT through his Consumer Protection and Public Health Division in the name of the STATE OF TEXAS and in the public interest under

the authority granted to him by §§ 431.047 and 431.0585 of the Texas Food, Drug and Cosmetic Act (“TFDCA”) and any regulations promulgated pursuant to this law, upon the grounds that the Commissioner of the Texas Department of State Health Services (“DSHS”) and his authorized agents find that Defendants have violated and are threatening to violate provisions of the TFDCA.

3. This suit is also brought by Attorney General GREG ABBOTT through his Consumer Protection and Public Health Division in the name of the State of Texas under the authority granted to him by § 17.47 of the Texas Deceptive Trade Act, TEX. BUS. & COM. CODE ANN. § 17.47 *et seq.*, (“DTPA”) upon the grounds that Defendants have engaged in false, misleading and deceptive acts and practices in the conduct of trade or commerce as defined and declared unlawful by § 17.46 (a) and (b) of the DTPA.

#### **DEFENDANTS**

4. Defendant BLISS W. CLARK, M.D., P.A. d/b/a CLARK ORTHOPEDICS & REHABILITATION is a for profit corporation engaged in business in Texas at 5505 S. Expressway 77/83 No. 304, Harlingen, Texas 78586. No service is required at this time.

5. Defendant BLISS W. CLARK, Individually, is a resident of the State of Texas and is an owner and/or representative in charge of CLARK ORTHOPEDICS & REHABILITATION and is engaged in business in Texas at 5505 S. Expressway 77/83 No. 34, Harlingen, Texas 78586. No service is required at this time.

#### **AUTHORITY**

6. This Court has jurisdiction of this action pursuant to TEX. HEALTH AND SAFETY CODE §§ 431.047(b) and 431.0585(a); and TEX. BUS. & COM. CODE ANN. § 17.47; and the authority granted to the Attorney General of Texas under the Constitution and the laws of the State of Texas.

### VENUE

7. Venue is proper in Bexar County under TEX. HEALTH & SAFETY CODE § 431.047 (a) - (d) because the violations and threats of violation have occurred in Bexar County, Texas; and
8. Venue is also proper in Bexar County under TEX. BUS. AND COM. CODE § 17.47(b) because the violations occurred in Bexar County, Texas and Defendants do business in Bexar County, Texas.

### PUBLIC INTEREST

9. Plaintiff, the STATE OF TEXAS, has reason to believe that the Defendants have engaged in, and will continue to engage in, the unlawful practices set forth below, and unless enjoined from doing so, such continued operations pose a threat to the public health and safety and will also cause adverse effects to legitimate business enterprises which lawfully conduct trade and commerce in this State. Therefore, the Consumer Protection and Public Health Division of the Office of the Attorney General believes, and is of the opinion, that these proceedings are in the public interest.

### NOTICE BEFORE SUIT

10. Pursuant to § 17.47 (a) of the Deceptive Trade Practices Act, contact has been made with the Defendants herein to inform them of the unlawful conduct alleged herein, by letter mailed by certified mail, return receipt requested, and regular mail at least seven days before filing suit.

### TRADE AND COMMERCE

11. Defendants are engaged in conduct which constitutes “trade” and “commerce” as those terms are defined by Section 17.45(6) of the DTPA, in that they were and are engaged in the business of receiving and introducing into commerce medical devices or more specifically, providing and injecting patients with such devices.

### ACTS OF AGENTS

12. Whenever in this petition it is alleged that Defendants BLISS W. CLARK, M.D., P.A. D/B/A CLARK ORTHOPEDICS & REHABILITATION and BLISS W. CLARK, INDIVIDUALLY did any act or thing, it is meant that Defendants performed or participated in such act or thing or that such act was performed by agents or employees of Defendants and in each instance, the agents or employees of Defendants were then authorized to and did in fact act on behalf of Defendants or otherwise acted under the guidance and direction of Defendants.

### FACTUAL ALLEGATIONS

13. On April 27, 2009, DSHS conducted an inspection of BLISS W. CLARK, M.D., P.A. d/b/a CLARK ORTHOPEDICS & REHABILITATION. This inspection was conducted as a result of an investigation of Elite Med, L.L.C., a New Braunfels, Texas firm not licensed as a device distributor as required by the State of Texas and engaged in the importing and distribution of medical devices not adequately labeled for sale in the United States.

14. BLISS W. CLARK, M.D., P.A. d/b/a CLARK ORTHOPEDICS & REHABILITATION is a clinic which provides comprehensive care to Texas consumers with degenerative disorders of the hip and knee. Defendants are customers of Elite Med, L.L.C. and DSHS investigated Defendants to determine the exact relationship between the two establishments, what products were purchased from Elite Med, L.L.C. and to examine any products that may still be in Defendants' inventory.

15. During the course of the investigation, it was discovered that Defendants had purchased Orthovisc, Synvisc and Hyalgan, all cleared for marketing by FDA as prescription devices, specifically arthritis injections. All of these medical devices are similar in that they are all injections and are used to provide pain relief suffered by consumers/patients with arthritis of the knee.

16. Defendants BLISS W. CLARK, M.D., P.A. d/b/a CLARK ORTHOPEDICS &

REHABILITATION and BLISS W. CLARK, Individually, have been purchasing these medical devices from Elite Med, L.L.C... Elite Med, L.L.C. is located in Texas and are not licensed to operate as a distributor of devices in Texas as required by law. Therefore, all devices purchased from this unlicensed distributor located in Texas violates state law.

17. Defendants had, in their possession at the time of the DSHS investigation, 41 units of Orthovisc and 34 units of Hyalgan, all of which had been purchased from Elite Med, L.L.C. (See Exhibit 1). After obtaining samples of the Hyalgan product, DSHS was able to determine that the product that Defendants were in possession of was for distribution only in Turkey. The Hyalgan, had labeling that was in a foreign language. (See Exhibit 1, *attached hereto and incorporated herein*). The product insert was written in a foreign language, and thus, the device is misbranded. (See Exhibit 2, *attached hereto and incorporated herein*).

18. In addition to some of the labeling not being in English, the labeling of the Hyalgan purchased and used by Defendants also lacked the required federal caution statement for prescription devices (legend), the product description, indications for use, contraindications, warnings, precautions, and patient disclosure information (e.g., indications, restrictions, and possible complications) on the insert since it was in a language other than English.

19. The Orthovisc in Defendants' possession was also purchased from Elite Med, L.L.C., and some had lot numbers that were for distribution in Turkey only. Additionally, all of the Orthovisc lacked an insert containing the product description, indications for use, contraindications, warnings, precautions, and patient disclosure information (e.g., indications, restrictions, and possible complications). All of Defendants' Orthovisc found in Defendant's possession at the inspection also lacked the required federal caution statement for prescription devices (legend).

20. On the date of inspection, DSHS sampled 41 units of Orthovisc and 34 units of Hyalgan. All

lot numbers of these medical devices were confirmed with the manufacturer to have been manufactured for export only. Additionally, Elite Med has provided invoices to the State of Texas indicating that Clark Orthopedics had previously purchased from January 2008 until March 2009, 110 Hyalgan kits, 25 Synvisc syringes, and 50 Orthovisc syringes.

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**APPLICABLE LAWS**  
**TEXAS FOOD, DRUG AND COSMETIC ACT**

21. Both federal and state law have requirements for labels and labeling of prescription devices and failing to comply with such requirements misbrands the devices pursuant to Section 431.112 of the Texas Health & Safety Code. This provision declares that a “drug or device shall be deemed to be misbranded: (a)(1) if its labeling is false or misleading in any particular; or ..... (c) if any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; or ..... (e) unless its labeling bears adequate directions for use .

22. Prescription devices purchased or sold in Texas must have adequate directions for use by a layperson as required by 21 CFR § 801.5, or comply with one of the exemptions to this requirement found in 21 C.F.R. §801.109 (a)(1)(i) and (ii) as listed above and as adopted by the rules in Texas.

23. The prescription devices purchased, used, possessed, and held by Defendants BLISS W. CLARK, M.D., P.A. D/B/A CLARK ORTHOPEDICS & REHABILITATION and BLISS W. CLARK, INDIVIDUALLY, lost their exemption from the requirement to have adequate directions for use by a layperson **prior** to purchase by Defendants as these devices were not in the possession of a person or entity engaged lawfully (distributor license required in Texas) to distribute such devices in Texas or in the possession of a practitioner. Defendants purchased or obtained devices

from Elite Med and/or Brian Bailey and none of these entities or individual are licensed to distribute such devices in Texas as required by law.

24. Elite Med and/or Brian Bailey are not licensed as wholesale prescription device distributors in Texas and, therefore, cannot legally distribute devices in Texas, as prohibited by Section 431.021(x) of the Texas Health and Safety Code. Therefore, all of the devices purchased from these distributors are misbranded pursuant to Section 431.112(e)(1) of the Health and Safety Code in that these prescription devices are not in the hands of a licensed prescription device distributor as required to keep valid the exemption from adequate directions for use as required by federal law, prior to the purchase by Defendants, and even though Defendant BLISS W. CLARK is a licensed practitioner, he cannot purchase misbranded devices.

25. In addition to receiving the products from an unlicensed source, some of the prescription devices purchased and used by Defendants are also misbranded pursuant to Section 431.112 (a)(1) of the Texas Health & Safety Code because their labeling is false or misleading in any particular or (c) if any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

26. Federal regulations determine what should be on prescription device labels or labeling, including, but not limited to the following:

- A. 21 CFR 801.15 (c)(1) - required labeling to be in the English language;
- B. 21 CFR 801.109 (b) - labels lack federal caution statement for prescription devices (legend); and
- C. 21 CFR 801.109 (d) - labeling lacks required product description, indications for use,

contraindications, warnings, precautions, and patient disclosure information (e.g., indications, restrictions, and possible complications).

27. The failure to comply with these requirements on the label and in labeling not only misbrands the prescription devices purchased and used by Defendants, but also makes the labeling false or misleading in any particular which also misbrands the prescription devices.

28. Section 431.021 of the Texas Health and Safety Code declares unlawful and sets forth, in relevant part, as prohibited acts, the following:

(a) the introduction or delivery for introduction into commerce of any food, drug, device, or cosmetic that is adulterated or misbranded;.....

(c) the receipt in commerce of any food, drug, device, or cosmetic in commerce that is misbranded or adulterated.

29. Section 431.0585 of the Texas Health & Safety Code provides that a person who violates Section 431.021 is liable for a civil penalty not to exceed \$25,000 a day for each violation. The statute also provides that each day of violation constitutes a separate violation for purposes of penalty assessment.

30. Section 431.047 of the Texas Health & Safety Code provides that where a person has violated, is violating, or is threatening to violate the Chapter or rules adopted thereunder, the Court, upon petition, may grant any injunctive relief warranted by the facts.

31. To enforce these laws and regulations and Chapter 431 of the Texas Health & Safety Code, the DSHS Commissioner or authorized agents may inspect any establishment in which a device is being held for introduction into commerce or held after the introduction into commerce, to obtain information to determine whether the device is misbranded or adulterated or in violation of this chapter; to obtain necessary samples, and have access to and copy and verify the records required

to be maintained, pursuant to Section 431.042(a) and (b) of the Health & Safety Code.

### **TEXAS DECEPTIVE TRADE PRACTICES ACT**

32. The Deceptive Trade Practices Act provides that false, misleading, or deceptive acts or practices in the conduct of any trade or commerce are unlawful and subject to action by the Consumer Protection Division of the Office of the Attorney General. TEX. BUS. & COM. CODE ANN.

§ 17.46 (b) including:

- a. Causing confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods or services in violation of § 17.46 (b) (2);
- b. Causing confusion or misunderstanding as to affiliation, connection, or association with, or certification by, another in violation of § 17.46 (b) (3);
- c. Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have or that a person has a sponsorship, approval, status, affiliation, or connection which they not have or that a person has a sponsorship, approval, status, affiliation, or connection which he does not, in violation of § 17.46 (b) (5);
- d. representing good or services are of a particular standard, quality, or grade, or that goods, are of a particular style or model, if they are of another, in violation of § 17.46 (7).

33. The Deceptive Trade Practices Act further provides that in addition to a request for injunctive relief, the Consumer Protection Division may request civil penalties be paid to the State in an amount of not more than \$20,000 per violation. TEX. BUS. & COM. CODE ANN. 17.47.

34. The Deceptive Trade Practices Act further provides that if the act or practice that is the subject of the proceeding was calculated to acquire or deprive money or other property from a consumer who was 65 years of age or older when the act or practice occurred, an additional amount

of not more than \$250,000 per violation may be awarded in civil penalties. TEX. BUS. & COM CODE ANN. 17.47(c)(2).

**PROHIBITED ACTS**  
**TEXAS FOOD, DRUG, AND COSMETIC ACT VIOLATIONS**

35. Defendants BLISS W. CLARK, M.D., P.A. d/b/a CLARK ORTHOPEDICS & REHABILITATION and BLISS W. CLARK, INDIVIDUALLY, as set out above and incorporated herein by reference, are in violation of Chapter 431 of the Texas Health & Safety Code, as follows:

- a. the introduction or delivery for introduction into commerce of any device that is misbranded, in violation of Section 431.021 (a) and
- b. the receipt in commerce of any device in commerce that is misbranded, in violation of Section 431.021 (c).

**DECEPTIVE TRADE PRACTICE ACT VIOLATIONS**

36. Defendants, as set out above and incorporated herein by reference, and in the course of trade and commerce, have engaged in false, misleading and deceptive acts and practices declared unlawful by the DTPA as follows:

- a. By receiving and introducing into commerce a prescription device that was misbranded, Defendants have caused confusion as to the source, sponsorship, approval, or certification of goods or services, in violation of § 17.46 (b) (2);
- b. By receiving and introducing into commerce a prescription device that was misbranded, Defendants have caused confusion or misunderstanding as to the affiliation, connection, or association with or certification of the goods or services, in violation of § 17.46 (b) (3);
- c. By receiving and introducing into commerce a prescription device that was

misbranded, Defendants have represented that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have or that a person has a sponsorship, approval, status, affiliation or connection which he does not, in violation of § 17.46 (b) (5);

d. ~~By receiving and introducing into commerce a prescription device that was~~ misbranded, Defendants have represented that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another, in violation of § 17.46 (b) (7).

#### **APPLICATION FOR TEMPORARY INJUNCTION**

37. It is essential that the Court temporarily enjoin Defendants from continuing the conduct described in this petition. Defendants will continue to engage in business with unlicensed entities and engage in receiving and introducing into commerce misbranded medical devices in violation of Texas law, unless restrained by this Court, and cause immediate, irreparable injury, loss and damage to the State of Texas and to the general public.

#### **APPLICATION FOR PERMANENT INJUNCTION**

38. It is essential that the Court permanently enjoin Defendants from continuing the conduct described in this petition. Defendants will continue to engage in business with unlicensed entities and engage in receiving and introducing into commerce misbranded medical devices in violation of Texas law.

#### **PRAYER**

39. For these reasons, the State requests that the Court upon notice and hearing issue a Temporary Injunction and upon final trial issue a Permanent Injunction enjoining Defendants, their

officers, agents, assigns, servants, employees and attorneys and any other person in active concert or participation with Defendants from engaging, directly or indirectly, in the following acts or practices:

**TEMPORARY INJUNCTION**

- A) ~~Transferring, concealing, destroying, or removing from the jurisdiction of this Court~~ any books, records, documents, invoices or other written materials relating to the business of Defendants, currently or hereafter in their possession, custody or control except in response to further orders or subpoenas in this cause;
- B) Interfering with, preventing, or in any way obstructing agents of the Texas Department of State Health Services from reasonably inspecting, copying, or photographing all business records and business premises of Defendants and all product found there, and pursuant to TEX. HEALTH & SAFETY CODE Chapter 431; the State's agents shall be allowed to temporarily remove, for a period not to exceed 24 hours, these records or devices to effectuate the copying or inspection of these records or devices;
- C) Purchasing any prescription devices from any entity or person or their agents or employees not located in Texas without first verifying that the entity or person are regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device as required by 21 CFR 801.109;
- D) Purchasing any prescription devices from any entity or person or their agents or employees located in Texas without first verifying that the distributor or manufacturer has a license issued by the Texas Department of State Health Services pursuant to this chapter;
- E) Receiving a misbranded device in commerce;
- F) Introducing or delivering for introduction into commerce a misbranded device;

- G) Receiving or introducing or delivering for introduction into commerce a device that is not labeled in English;
- H) Receiving or introducing or delivering for introduction into commerce a device that lacks the required federal caution statement for Rx devices (legend);
- ~~I) Receiving and introducing or delivering for introduction into commerce a~~  
prescription device that has labeling that lacks the FDA required product description, indications for use, contraindications, warnings, precautions, and patient disclosure information (e.g., indications, restrictions, and possible complications);
- J) Receiving and introducing or delivering for introduction into commerce a device that is labeled only for distribution in a country other than the United States;
- K) Causing confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods or services
- L) Causing confusion or misunderstanding as to affiliation, connection, or association with, or certification, by another;
- M) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have or that a person has a sponsorship, approval, status, affiliation, or connection which he does not; and
- N) Representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another.

### **PERMANENT INJUNCTION**

- A) Purchasing any prescription devices from any entity or person or their agents or employees not located in Texas without first verifying that the entity or person are regularly

and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device as required by 21 CFR 801.109;

B) Purchasing any prescription devices from any entity or person or their agents or employees located in Texas without first verifying that the distributor or manufacturer has a license issued by the Texas Department of State Health Services pursuant to this chapter;

C) Receiving a misbranded device in commerce;

D) Introducing or delivering for introduction into commerce a misbranded device;

E) Receiving or introducing or delivering for introduction into commerce a device that is not labeled in English;

F) Receiving or introducing or delivering for introduction into commerce a prescription device that lacks the required federal caution statement for Rx devices (legend);

G) Receiving and introducing or delivering for introduction into commerce a prescription device that has labeling that lacks the FDA required product description, indications for use, contraindications, warnings, precautions, and patient disclosure information (e.g., indications, restrictions, and possible complications); and

H) Receiving and introducing or delivering for introduction into commerce a prescription device that is labeled only for distribution in a country other than the United States.

I) Causing confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods or services

J) Causing confusion or misunderstanding as to affiliation, connection, or association with, or certification, by another;

K) Adjudge against Defendants, jointly and severally, civil penalties in favor of Plaintiff

in an amount of not more than \$25,000.00 per violation pursuant to TEX. HEALTH & SAFETY CODE § 431.0585 (b);

L) Adjudge against Defendants, jointly and severally, civil penalties in favor of Plaintiff in an amount of not more than \$20,000.00 per violation of the DTPA;

M) Order Defendants, jointly and severally, to pay reasonable expenses incurred by Texas Department of State Health Services in obtaining any injunctive relief including investigation costs, court costs, and other expenses pursuant to TEX. HEALTH & SAFETY CODE § 431.047 (d);

N) Order Defendants, jointly and severally, to pay Plaintiff attorney fees, costs of court and expenses pursuant to TEX. GOVT. CODE, § 402.006(c) and TEX. HEALTH AND SAFETY CODE § 431.047 (d);

O) Order Defendants, jointly and severally, to pay pre-judgment interest on all awards of restitution, damages or civil penalties, as provided by law; and

P) Grant all other relief to which Plaintiff State of Texas may show itself entitled.

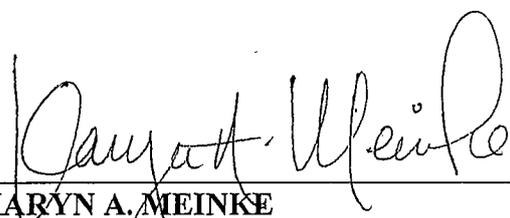
Respectfully submitted,

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**ATTORNEYS FOR PLAINTIFF**

# Hyalgan<sup>®</sup>

Hyaluronik asit sodyum tuzu



Intra-artiküler enjeksiyon için  
1 adet kullanıma hazır enjektör



STATE'S  
EXHIBIT

**tebilim**  
ILAC SAN. VE TIC. A.Ş.

# HYALGAN®

Intra-artiküler enjeksiyon için steril çözelti  
içeren kullanıma hazır enjektör

## FORMÜLÜ:

Her enjektör:

20 mg/2 ml hiyaluronik asit sodyum tuzu içerir. Ayrıca 0,1 mg sodyum dihidrojen fosfat dihidrat, 1,2 mg disodyum monohidrojen fosfat dodekahidrat, 17 mg sodyum klorür, k.m. 2 ml enjeksiyonluk su içerir.

## FARMAKOLOJİK ÖZELLİKLERİ:

### Farmakodinamik Özellikleri:

HYALGAN®, hiyaluronik asidin; yüksek derecede saflaştırılmış, yüksek moleküler ağırlıklı, steril, non-projenik, viskoz, tamponlanmış aköz solüsyonudur. Hiyaluronik asit, vücut ekstrasellüler matrisinin önemli bir bileşendir. Özellikle kıkırdakta ve sinoviyal sıvıda yüksek konsantrasyonda bulunur. Endojen hiyaluronik asit, eklemden kayganlaştırıcı ve şok absorbe eden temel yapı sinoviya sıvısının viskozite ve elastikiyetini sağlamaktadır. Ayrıca, eklem kıkırdağındaki proteoglikanların düzgün yapısı için gereklidir. Osteoartritte, eklem kıkırdağı ve sinoviyal sıvıda bulunan hiyaluronik asidin miktarı azalmış ve kalitesi değişmiştir. Patolojik sinoviyal sıvı içeren, dejenerasyonlu eklem kıkırdağı yüzeyi olan artritlik eklemlere intraartiküler hiyaluronik asit uygulaması ile eklem işlevlerinde düzelme sağlanmaktadır. HYALGAN® tedavisi ile uzun süreli yararlar sağlandığı klinik çalışmalarda gösterilmiştir. Hyalgan, sinoviyositlerden endojen hiyaluronik asit salınımını artırmakta ve uzun süreli etki sağlamaktadır. Buna ek olarak, proteoglikan agregatlarının metabolizmasını da etkilemekte ve kondrositler, sinoviyositler ve diğer hücrelerin spesifik reseptörleri ile etkileşmektedir. HYALGAN®, insan eklem sıvısındaki enflamatuar ve ağrı medyatörlerini azaltarak, anti-enflamatuar ve analjezik etki gösterir. Yanısıra, oksidatif hasardan koruduğuna dair kanıtlar bulunmaktadır. Kontrollü klinik çalışmalarda, HYALGAN® ile yapılan tedavi siklusları sonucunda, tedavi bitiminden 6 ay sonrasına kadar osteoartrit semptomlarında iyileşme görülmüştür.

### Farmakokinetik Özellikleri:

Hiyaluronik asit sodyum tuzu, uygulandığı eklemden 2-3 gün içinde elimine edilir. Farmakokinetik çalışmalar, hızla sinoviyal membranda dağıldığını göstermiştir. İşaretili hiyaluronik asit, en yüksek konsantrasyonda sinoviya sıvısı, eklem kapsülü ve daha az olarak da sinoviyal membran, bağlar ve komşu eklemlerde bulunmuştur. Hiyaluronik asidin sinoviyal sıvıda önemli ölçüde metabolize olmadığı görülmektedir. Hayvan çalışmaları, eklem çevresindeki dokularda bir degradasyon olduğunu gösterdiyse de, temel metabolizasyon, karaciğerde olmakta ve böbrekler yoluyla atılmaktadır.

## ENDİKASYONLARI:

Diz osteoartritinde eklem disfonksiyonu ve ağrısında rahatlama sağlanması için kullanılmaktadır.

## KONTRENDİKASYONLARI:

Ürünün içeriğindeki maddelere veya tavuk proteinlerine karşı bilinen aşırı duyarlılığı olanlara uygulanmamalıdır. Başka preparatlara bilinen aşırı duyarlılığı olanlarda ise yarar/zarar değerlendirildikten sonra kullanılmalıdır.

Enjeksiyon yeri veya eklemde enfeksiyon veya deri hastalığı olanlarda uygulanması kontrendikedir.

İntravasküler enjeksiyon için geçerli diğer tüm kontrendikasyonların olduğu durumlarda da uygulanmamalıdır.

Özellikle akut inflamatuvar eklem hastalarında kullanılmamalıdır.

