

# Medical Information for Patients and Healthcare Personnel

患者と医療者のための医療情報

Tokyo Institute of Technology

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2018年に500万人の高齢者が薬物有害事象で受診



42%の高齢者が5剤以上を服用



過去20年間でポリファーマシーが300%増



薬物有害事象のため毎日750人が入院



10年間の不要な入院で620億ドル



薬物有害事象で次の10年で15万人死亡



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# Escitalopram

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## エスシタロプラム(レクサプロ)

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## 1. About escitalopram

Escitalopram is a type of antidepressant known as a selective serotonin reuptake inhibitor (SSRI).

It's often used to treat [depression](#) and is sometimes used for [anxiety](#), [obsessive compulsive disorder](#) or [panic attacks](#).

Escitalopram helps many people recover from depression and has fewer unwanted effects than older antidepressants.

Escitalopram is available on prescription. It comes as tablets and liquid drops that you put in a drink.

## 2. Key facts

- It usually takes 4 to 6 weeks for escitalopram to work.
- Side effects such as feeling sick (nausea) and headache are common. They're usually mild and go away after a couple of weeks.
- If you and your doctor decide to take you off escitalopram, your doctor will probably recommend reducing your dose gradually to help prevent extra side effects.
- Escitalopram is also called by the brand name Cipralex.

1 エスシタロプラムについて  
エスシタロプラムはSSRIとして知られている抗うつ薬です。うつ病の治療のために使用されることが多く、不安、強迫性障害、パニック障害に使用されることもあります。(以下略)

## 2 鍵となる事実

- ・作用するのに通常4～6週間かかります
- ・悪心や頭痛といった副作用は一般的です。通常は軽症で1～2週でおさまります。(以下略)

### 3. Who can and can't take escitalopram

Escitalopram can be taken by adults over the age of 18.

Check with your doctor before starting to take escitalopram if you:

- have had an allergic reaction to escitalopram or any other medicines in the past
- have [epilepsy](#) or are having electroconvulsive treatment - escitalopram may increase your risk of having a seizure
- have a heart problem - escitalopram can speed up or change your heartbeat
- have a low heart rate, plus you have had severe [diarrhoea and vomiting](#) for a long time or take tablets that make you pee more (diuretics)

3 服用できる人、できない人  
エスシタロプラムは18歳以上の成人が服用できます。服用する前に医師と以下をチェックしましょう。

- ・過去にエスシタロプラムまたは他の薬にアレルギー反応を起こした
- ・てんかんがある、または電気けいれん療法を受けている一発作のリスクが高まるかもしれません
- ・心臓に問題がある一心拍数を上げる/変動させるかもしれません (以下略)

- have ever taken any other medicines for depression - some rarely used antidepressants can interact with escitalopram to cause very [high blood pressure](#) even when they have been stopped for a few weeks
- are trying to become pregnant, already pregnant or breastfeeding
- have an eye problem called [glaucoma](#) - escitalopram can increase the pressure in your eye

If you have [diabetes](#), escitalopram can make it more difficult to keep your blood sugar stable.

Monitor your blood sugar more often for the first few weeks of treatment with escitalopram and adjust your diabetes treatment if necessary.

## 4. How and when to take it

Take escitalopram once a day. You can take it with or without food.

You can take escitalopram at any time of day, as long as you stick to the same time every day.

If you have trouble sleeping, it's best to take it in the morning.

### How much to take

・うつ病に対して他の薬を飲んだことがあるーまれにエスシタロプラムとの相互作用で血圧が上昇することがある  
・妊娠を希望、すでに妊娠または授乳している  
・緑内障ーエスシタロプラムが眼圧を上げる可能性がある（以下略）

4 いつ、どのように飲むか  
1日1階飲んでください。食べ物といっしょでもかまいません。  
同じ時間であれば1日のうちいつ飲んでもかまいません（以下略）



Escitalopram tablets come in different strengths ranging from 5mg to 20mg.

The usual dose of escitalopram is 10mg a day in adults. But you may start on a lower dose and increase to a maximum dose of 20mg a day.

If you have liver problems, the maximum recommended dose is 10mg a day.

With liquid drops of escitalopram, 1 drop is equivalent to 1mg, 10 drops is 10mg, 20 drops is 20mg.

### What if I forget to take it?

Do not take a double dose to make up for forgotten doses.

If you do forget to take a dose and remember before you go to bed, take it straight away. Carry on as usual the next day.

If you only remember during the night or the next day, leave out the missed dose and carry on as usual.

If you forget doses often, it may help to set an alarm to remind you.

You could also ask your pharmacist for advice on other ways to help you remember to take your medicine.

Wh

エスシタロプラム錠は5mgから20mgがあります。成人では通常1日10mgです。しかし、少量から初めて最大20mgになることもあります。液体の場合、1滴が1mgです。10滴なら10mg、20滴なら20mgです。

飲むのを忘れたら  
忘れた分とあわせて2倍量を服用しないでください  
飲むのを忘れて寝る前に  
思い出したらすぐ飲んでください。翌日は通常通りにしてください(以下略)

## What if I take too much?

The amount of escitalopram that can lead to an overdose varies from person to person.

### Call your doctor straight away if:

You have taken too much escitalopram by accident and experience symptoms such as:

- feeling agitated
- being sick (vomiting)
- shaking
- a fast heart rate
- seizures

If you need to go to [A&E](#) straight away, do not drive yourself - get someone else to drive you or call for an ambulance.

Take the escitalopram packet or the leaflet inside it, plus any remaining medicine, with you.

飲み過ぎたら？  
過量となる量は人によって  
違います。

以下ならすぐ医師に電話し  
てください

うっかり飲み過ぎて以下の  
症状が起きたら

- ・不穏
- ・気分が悪い(嘔吐)
- ・ふるえ
- ・ドキドキする
- ・てんかん発作

救急病院に行く必要がある  
場合、自分では運転しない  
でください

エシタロプラムの包装ま  
たは添付文書、残りの薬を  
持参してください

## 5. Side effects

Like all medicines, escitalopram can cause side effects in some people, but many people have no side effects or only minor ones.

Some of the common side effects of escitalopram will gradually improve as your body gets used to it.

### Common side effects

Common side effects may happen in more than 1 in 10 people.

Keep taking the medicine, but talk to a doctor or pharmacist if these side effects bother you or don't go away:

- a dry mouth
- sweating a lot
- being unable to sleep
- feeling sleepy
- feeling tired or weak

## 5 副作用

他の薬と同様、エシタロプラムで副作用を起こす人もいますが、たいていは副作用がないか、あってもわずかです。

エシタロプラムの一般的な副作用のいくつかは慣れれば次第に回復します

### 一般的な副作用

一般的な副作用は10人中1人以上に起こる可能性があります

服用は続けて、つらくて治まらないようなら医師か薬剤師に話してください。

- ・口のかわき
- ・大量の汗
- ・眠れない
- ・眠気（以下略）

## Serious side effects

Serious side effects are rare and happen in less than 1 in 1,000 people.

### Go to A&E immediately if you get:

- painful erections that last longer than 4 hours - this may happen even when you're not having sex
- severe dizziness or passing out
- any bleeding that's very bad or you can't stop, such as cuts or nosebleeds that don't stop within 10 minutes

### Call a doctor straight away if you get:

- constant [headaches](#), long-lasting confusion or weakness, or frequent muscle cramps - these can all be signs of low sodium levels in your blood (in severe cases, low sodium can lead to seizures)
- thoughts about harming yourself or ending your life
- a high temperature (38C and above) with agitation, confusion, trembling and twitching
- vomiting blood, coughing up vomit, blood in your pee, black or red poo - these can be signs of bleeding from the gut
- bleeding from the gums, or bruises that appear without a reason or get bigger

## 重大な副作用

重大な副作用はまれで、1000人中1人未満に起きます

すぐに救急病院に行ってください

- ・痛みのある勃起が4時間以上続く セックスをしていなくても起こることがあります
- ・ひどいめまい、気を失う  
(以下略)

すぐに医師に電話してください

- ・頭痛、錯乱が続く、筋肉のけいれん

- ・自傷、自殺について考える
- ・錯乱、震えを伴う38度以上の発熱
- ・血液を吐く、尿に血が混じる、黒または赤の便  
(以下略)

**Book an appointment with your doctor if you experience:**

- weight gain or loss without trying
- changes in your periods, such as heavy bleeding, spotting or bleeding between periods

### **Serious allergic reaction**

In rare cases, it's possible to have a serious allergic reaction ([anaphylaxis](#)) to escitalopram.

### **Contact a doctor straight away if:**

- you get a skin rash that may include itchy, red, swollen, blistered or peeling skin
- you're wheezing
- you get tightness in the chest or throat
- you have trouble breathing or talking
- your mouth, face, lips, tongue or throat start swelling

These are warning signs of a serious allergic reaction.

A serious allergic reaction is an emergency.

医師の予約をとってください

- ・体重増加、または減少
- ・生理不順、生理が重い、生理中でないのに出血がある

重大なアレルギー反応

まれですが重大なアレルギー反応(アナフィラキシー)を起こすことがあります

すぐ医師を読んでください

- ・発疹(かゆくて赤く、腫れあがった、水疱を伴う、皮がはがれた)
- ・喘鳴がある
- ・胸やのどが苦しい  
(以下略)

These aren't all the side effects of escitalopram.

For a full list, see the leaflet inside your medicines packet.

You can report any suspected side effect to the [UK safety scheme](#).

## 6. How to cope with side effects

What to do about:

- **a dry mouth** - chew sugar-free gum or sugar-free sweets
- **sweating a lot** - try wearing loose clothing, using a strong anti-perspirant, and keeping cool using a fan, if possible. If this doesn't control the problem, talk to your doctor. You may need to try a different antidepressant.
- **being unable to sleep** - take escitalopram first thing in the morning
- **feeling sleepy** - take escitalopram in the evening and cut down the amount of alcohol you drink. Do not drive or use tools or machinery if you're feeling sleepy. If this doesn't help, talk to your doctor.
- **feeling tired or weak** - stop what you're doing and sit or lie down until you feel better. Do not drive or use tools or machinery if you're feeling tired. Do not drink alcohol as it'll make you feel worse.

これらは副作用のすべてではありません。すべてのリストは薬の包装の中に入っているリーフレットを見てください

副作用をうたがったら「UK safety scheme」に報告することができます

### 6 副作用の対処法

- ・口がかわく: 砂糖を含まないガムやお菓子を食べる
- ・汗をかく: ゆったりした服を着て扇風機などで涼しくする、よくならなければ医師に相談してください。別の抗うつ薬を試す必要があるかもしれません
- ・眠れない: 朝に服用する  
(以下略)

## 7. Pregnancy and breastfeeding

It's important for you and your baby that you stay well during your pregnancy.

If you become pregnant while taking escitalopram, speak to your doctor. Do not stop taking your medicine unless your doctor tells you to.

Escitalopram has been linked to a very small increased risk of problems for your unborn baby.

But if your depression isn't treated during pregnancy, this can also increase the chance of problems.

You may need to take escitalopram during pregnancy if you need it to remain well.

Your doctor can explain the risks and the benefits, and will help you decide which treatment is best for you and your baby.

For more information about how escitalopram can affect you and your baby during pregnancy, [read this leaflet on the best use of medicines in pregnancy \(BUMPS\) website](#).

## 7 妊娠と授乳

あなたとあなたの赤ちゃんのために、妊娠中も健やかでいることが重要です

エスシタロプラム服用中に妊娠したら医師に話してください。医師の指示がなければ薬をやめないでください

エスシタロプラムはわずかですがまだ生まれていない赤ちゃんに問題が生じるリスクの上昇と関係しています  
ですが妊娠中にうつ病の治療が行われなければ、これも問題の起こる可能性を高めます

健やかにいるために薬が必要ならエスシタロプラムを服用する必要があります  
(以下略)

## Escitalopram and breastfeeding

If your doctor or health visitor says your baby is healthy, escitalopram can be used during breastfeeding.

Escitalopram passes into breast milk in small amounts, and has been linked with side effects in very few breastfed babies.

It's important to continue taking escitalopram to keep you well. Breastfeeding will also benefit both you and your baby.

If you notice that your baby isn't feeding as well as usual, seems unusually sleepy or you have any other concerns about your baby, talk to your health visitor or doctor as soon as possible.

### Tell your doctor if you're:

- trying to get pregnant
- pregnant
- breastfeeding

エスシタロプラムと授乳  
もし医師やhealth visitorがあ  
なたの赤ちゃんは健康だと言  
えば、授乳中も薬を続けられ  
ます

エスシタロプラムは少量です  
が母乳に混ざり、ごくまれに  
副作用と関係します

あなたが健やかであるため  
にエスシタロプラムの服用を  
続けることが重要です。母乳  
もまたあなたと赤ちゃんの両  
方にとって有益です

もし赤ちゃんがいつものよう  
に飲まなかったり、異常に眠  
そうだったり、その他心配なこ  
とがあれば、すぐに医師また  
はhealth visitorに相談してく  
ださい

(以下略)



## 8. Cautions with other medicines

Some medicines and escitalopram can interfere with each other and increase the chances of you having side effects.

**Tell your doctor if you're taking these medicines before you start escitalopram:**

- any medicines that affect your heartbeat - escitalopram can speed up or change your heartbeat
- any other medicines for depression - some rarely used antidepressants can interact with escitalopram to cause very high blood pressure even when they have been stopped for a few weeks

These aren't all the medicines that can interfere with escitalopram.

For a full list, see the leaflet inside your medicine packet or check with your pharmacist.

### Mixing escitalopram with herbal remedies and supplements

Do not take St John's wort, the herbal remedy for depression, while you're being treated with escitalopram as this will increase your risk of side effects.

8 他の薬との相互作用  
ある薬とエスシタロプラムは相互に反応し、副作用の可能性を高めます

以下の薬を飲んでいたら、エスシタロプラムを開始する前に医師に伝えてください

・心拍に関係する薬－エスシタロプラムが心拍を速めることがあります

・うつ病の他の薬－めったに使われないうつ病薬がエスシタロプラムと相互作用を起こし血圧を非常に高めるかもしれません(以下略)

エスシタロプラムとハーブやサプリメントとの混合

エスシタロプラム服用中はセント・ジョーンズ・ワートを飲まないでください(以下略)

## Important

Tell your doctor or pharmacist if you're taking any other medicines, including herbal remedies, vitamins or supplements.

## 9. Common questions

- ▶ [How does escitalopram work?](#)
- ▶ [When will I feel better?](#)
- ▶ [How will it make me feel?](#)
- ▶ [How long will I take it for?](#)
- ▶ [How do I come off escitalopram?](#)
- ▶ [Is it safe to take it for a long time?](#)
- ▶ [Is escitalopram better than other antidepressants?](#)
- ▶ [What's the difference between escitalopram and citalopram?](#)
- ▶ [Will I gain or lose weight?](#)

## 重要

ハーブ、ビタミン、サプリメントを含め、他の薬を飲んでいたら医師または薬剤師に伝えてください

## 9 一般的な質問

- ・エスシタロプラムはどのように作用するのか？
- ・いつ気分がよくなるのか？
- ・どのように感じるのか？
- ・どのくらいの期間飲むのか？（以下略）

- ▶ [Can I drive or ride a bike?](#)
- ▶ [Will it affect my contraception?](#)
- ▶ [Will it affect my fertility?](#)
- ▶ [Will it affect my sex life?](#)
- ▶ [Can I drink alcohol with it?](#)
- ▶ [Is there any food or drink I need to avoid?](#)
- ▶ [Are there other treatments that will help?](#)
- ▶ [Will recreational drugs affect it?](#)

### Related conditions

- [Clinical depression](#)
- [Generalised anxiety disorder in adults](#)
- [Obsessive compulsive disorder \(OCD\)](#)
- [Panic disorder](#)

- ・自動車やバイクの運転はできるのか？
- ・避妊薬に影響があるのか？
- ・妊娠に影響があるのか？
- ・性生活に影響があるのか？
- ・お酒を飲んでもよいのか？
- ・避けたほうがよい食べ物や飲み物はあるのか？
- ・他に治療法はあるのか？
- ・レクリエーション薬は影響するのか？

### 関連する病気

- ・臨床的うつ
- ・成人の全般性不安障害
- ・強迫性障害
- ・パニック障害

## Useful resources

- [Antidepressants: videos of real stories](#)
- [Depression Alliance: charity](#)
- [Depression UK: charity](#)
- [Depression: videos of real stories](#)
- [Escitalopram: forums](#)
- [Mind: charity](#)
- [Samaritans: charity for help and support](#)

## 有用な情報源

- 抗うつ薬：リアルストーリーのビデオ
- Depression Alliance：チャリティー団体
- Depression UK：チャリティー団体
- うつ病：リアルストーリーのビデオ
- エシタロプラム：フォーラム
- Mind：チャリティー団体
- Samaritans：支援のチャリティー団体

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# Implicit assumption

暗黙の考え

# Common question:

よくある質問

How effective is this  
drug likely to be for my  
condition?

この薬は私の病気にどのくらい効くの？



# Lexapro

Lexapro for Major Depression

OVERVIEW TRIALS SIDE EFFECTS LIFESTYLE CHANGES

## Benefits and Side Effects Seen in Drug Approval Trials

### 成人のうつ病に対するレクサプロvsプラセボ

## Lexapro vs. Placebo for major depression in adults

FDA reviewed one main trial done in the U.S. and one supportive trial in Europe for major depression which tested set doses. Data are from the main U.S. trial. People were randomized to either Lexapro 20mg, Lexapro 10mg, Citalopram (Celexa) 40mg or Placebo.

The data below are only for Lexapro 10mg (the recommended dose) vs Placebo. While FDA approved Lexapro 20mg, this higher dose was not more effective than 10mg.



# 臨床試験の対象者は？

Who was in the trial?



**PATIENTS**

251 adults  
65% women

**AGE**

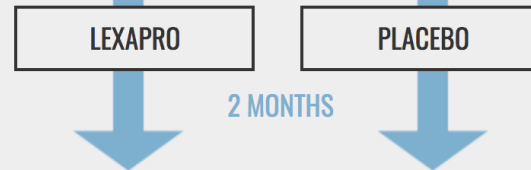
18 - 65 years  
average 40 years

**CONDITIONS**

Major depression  
Average MADRS score  
of 29 and average  
HAM-D score of 25  
Severity: Average time  
with depression 11  
years

# ランダム化試験

Randomized Trial



WHAT HAPPENED?

HIDE  
RESULTS

## Benefits

うつが軽減？

・うつ病尺度の変化  
(0-60)



**Change in depression - on a scale from 0 [no depression] to 60 [severe depression]**

LEXAPRO  
10mg once a day

13 points less depressed

PLACEBO  
No drug

9 points less depressed

LEXAPRO vs. PLACEBO

LEXAPRO helped  
4 points less depressed on the 61-point scale

・うつ病尺度の点数  
(0-60)



**Depression score - on a scale from 0 [no depression] to 60 [severe depression]**

16 points  
("Mild depression")

20 points  
("Moderate depression")

LEXAPRO helped  
4 points less depressed on the 61-point scale

・うつ病尺度の変化  
(0-76)



**Change in depression - on a scale from 0 [no depression] to 76 [severe depression]**

11 points less depressed

8 points less depressed

LEXAPRO helped\*  
3 points less depressed on the 77-point scale

・うつ病尺度の点数  
(0-76)



**Depression score - on a scale from 0 [no depression] to 76 [severe depression]**

14 points

17 points

LEXAPRO helped\*  
3 points less depressed on the 77-point scale

## 患者の評価

Not measured

測定されていない

## 医師の評価

うつ病重症度  
の変化(1-7)



**Change in depression severity - on a scale from 1 [normal] to 7 [most severe]**

1.3 points less severe

0.8 points less severe

LEXAPRO helped\*  
0.5 points less severe on the 7-point scale

うつ病重症度  
(1-7)



**Depression severity - on a scale from 1 [normal] to 7 [most severe]**



2.9 points  
(Between "borderline" and "mildly ill")

3.4 points  
(Between "mildly ill" and "moderately ill")

LEXAPRO helped\*  
0.5 points less severe on the 7-point scale

Benefit data are from the trial SCT-MD-01 in the FDA review (NDA#021323-S000). \*This conclusion is not included in the FDA-approved package insert (which may be based on other criteria or analyses).

# Side Effects 副作用

	LEXAPRO 10mg once a day	PLACEBO No drug	LEXAPRO vs. PLACEBO	
<p><b>Black Box Warning - FDA's most serious alert</b></p> <p><b>最も重篤</b></p> 	<p><b>Suicidal thoughts and attempts in children, teenagers, and young adults</b></p> <p><b>小児、十代、若者の自殺企図</b></p>		<p>LEXAPRO – like all anti-depressants – can increase suicidal thoughts and attempts in adolescents and young adults: For every 1,000 adolescents taking antidepressants, 14 more will become suicidal than if they took placebo. In young adults, those numbers are 5 in 1,000.</p>	
<p><b>Serious</b></p> <p><b>重篤</b></p> 	<p><b>Manic episodes (abnormally elevated mood or hyperactivity) in people treated for depression or other mood disorders in the past</b></p>	0.1%	0%	<p>Extra 0.1% of people had activation of mania or hypomania from LEXAPRO</p>

**躁エピソード**

**Angle-closure  
glaucoma**

**閉塞隅角緑内障**

Data not reported

**Easy bruising and  
bleeding (which can  
be serious)**

**内出血、出血**

Data not reported

**Low sodium levels**

**低ナトリウム**

Data not reported

**Seizure**

**てんかん**

Data not reported

**May cause a life-  
threatening condition  
(Serotonin syndrome)**

**生命にかかわる病気**

Data not reported

Most common symptom  
side effects highlighted by  
FDA



FDAにより強  
調されたよく  
ある有症状  
副作用

オーガズ ムの遅れ	9%	<1%	Extra 8.5% of people had delayed orgasm, lack of interest in sex, or problems having an erection with LEXAPRO
悪心	15%	7%	Extra 8% of people had nausea with LEXAPRO
不眠	9%	4%	Extra 5% of people had insomnia with LEXAPRO
眠気	6%	2%	Extra 4% of people had drowsiness with LEXAPRO
疲労	5%	2%	Extra 3% of people had fatigue with LEXAPRO
多汗	5%	2%	Extra 3% of people had increased sweating with LEXAPRO
性衝動の 減少	3%	1%	Extra 2% of people had a decreased desire for sex with

オーガズムが  
得られない

2%

<1%

Extra 1.5% of people  
could not have an  
orgasm with  
LEXAPRO

Other possible  
side effects

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Serious and symptom side effects are from all placebo-controlled trials of Lexapro for major depressive disorder involving 1,307 people in FDA-approved package insert (October 2014). Could not have an orgasm data is from all placebo-controlled trials of LEXAPRO involving 894 women in the FDA-approved insert (October 2014). Black Box Warning side effect is from 319 pooled anti-depressant drug trials involving 81,400 people in the FDA-approved insert (October 2014).

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ARTICLE

Drug Fact Boxを用いて薬の益と害を示す:2つのRCT

# Using a Drug Facts Box to Communicate Drug Benefits and Harms

Two Randomized Trials

Lisa M. Schwartz, MD, MS; Steven Woloshin, MD, MS; and H. Gilbert Welch, MD, MPH



現在、米国の一般市民は、処方薬の有効性と副作用に関して、入手可能で正確な情報を欠いている。その代わりに、人々は新製品に対する熱狂を生み出すように作られた何十億ドルものマーケティング手法にさらされており、押しつけがましいマーケティング手法や情報の選択的な提示に対して脆弱なままである。対照群が薬の益を劇的に過大評価したことは驚くにあたらない。われわれの研究によると、ドラッグファクトボックスは、消費者が薬剤の効きめを評価し、現在の症状に対するよりよい薬剤の選択をもたらし、予防目的の投薬における益の過大評価を修正した。

FDAのリスクコミュニケーション諮問委員会および議会は、FDAに「Drug Fact Box」の実施を検討するよう求めた。残念ながら、FDAはエビデンスを検討するためにさらに3～5年が必要だと言った。その潜在的な公衆衛生上のインパクトを考えると、医師と一般市民はより良い医薬品情報を得るためにそれほど長く待つ必要はないはずだ。今すぐアクセスできるようにすべきだ。

Schwartz LM, Woloshin S. The Drug Facts Box: Improving the communication of prescription drug information. *Proc Natl Acad Sci USA*. 110 Suppl 3:14069-74, 2013 Aug 20.

実際、FDA自身の「エビデンスに基づくユーザー・コミュニケーション・ガイド」には、「治療の選択肢に関連するリスクと利益の数値的推定値を患者に提供することが不可欠だ」と書かれている。もしFDAが、FDAが承認する薬について知っていることと知らないことを明確かつ簡潔に伝えることができないなら、別の独立した団体が彼らのためにそれをすべき時である。

Schwartz LM, Woloshin S. The Drug Facts Box: Improving the communication of prescription drug information. *Proc Natl Acad Sci USA*. 110 Suppl 3:14069-74, 2013 Aug 20.